

EXHIBIT I

**THIS EXHIBIT CONTAINS CONFIDENTIAL OR
RESTRICTED CONFIDENTIAL INFORMATION
AND HAS BEEN SERVED VIA EMAIL.**

1 UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
2 CAMDEN VICINAGE
3 IN RE: VALSARTAN, LOSARTAN)
AND IRBESARTAN PRODUCTS)
4 LIABILITY LITIGATION) MDL NO. 2875
_____))
5) HON. ROBERT B.
THIS DOCUMENT RELATES TO:) KUGLER
6)
ALL ACTIONS)

7 _____
8
9 — — —
10 Tuesday, October 5, 2021
— — —

11
12 CONFIDENTIAL INFORMATION
13 SUBJECT TO PROTECTIVE ORDER
— — —

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15
16 Remote Video-Recorded Oral
Deposition of GEORGE JOHNSON, Ph.D.,
17 VOLUME 2, held at the location of the witness
commencing at 9:14 a.m. BST on the above
18 date, before Michael E. Miller, Fellow of the
Academy of Professional Reporters, Certified
19 Court Reporter, Registered Diplomate
Reporter, Certified Realtime Reporter, and
20 New Jersey Certified Court Reporter
No. 30XI00242200.

21
22 — — —
23 GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
24 deps@golkow.com

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17 Exhibit 2	477																		
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<p style="text-align: right;">Page 325</p> <p>1 -----</p> <p>2 PROCEEDINGS</p> <p>3 October 5, 2021, 9:14 a.m. BST</p> <p>4 -----</p> <p>5 THE VIDEOGRAPHER: This is the</p> <p>6 continued deposition of Dr. George</p> <p>7 Johnson. Today's date is</p> <p>8 October the 5th, 2021, and the time is</p> <p>9 9:14 a.m.</p> <p>10 -----</p> <p>11 GEORGE JOHNSON, Ph.D.,</p> <p>12 having been previously duly sworn,</p> <p>13 testified as follows:</p> <p>14 -----</p> <p>15 EXAMINATION</p> <p>16 -----</p> <p>17 BY MS. BOGDAN:</p> <p>18 Q. Good morning.</p> <p>19 A. Good morning.</p> <p>20 Q. Earlier here than there, but...</p> <p>21 MS. BOGDAN: Could we please</p> <p>22 pull up exhibit Technical Fact Sheet</p> <p>23 NDMA, EPA.</p> <p>24 (Whereupon, Deposition Exhibit</p>	<p style="text-align: right;">Page 327</p> <p>1 A. Not in depth. It wasn't</p> <p>2 entirely applicable to this scenario in my</p> <p>3 perspective.</p> <p>4 Q. Do you know if NDMA is used for</p> <p>5 commercial purposes in the United States as</p> <p>6 of now?</p> <p>7 A. I don't. I don't know.</p> <p>8 Q. Directing your attention to</p> <p>9 "What is NDMA" on this exhibit, the second</p> <p>10 bullet point down.</p> <p>11 A. Second bullet point, yeah, I</p> <p>12 can see that.</p> <p>13 Q. Okay. And that statement</p> <p>14 reads: NDMA is not currently produced in</p> <p>15 pure form or commercially used in the United</p> <p>16 States, except for research purposes.</p> <p>17 A. I can see that.</p> <p>18 Q. Okay. Is that statement on</p> <p>19 this EPA document surprising to you?</p> <p>20 A. That is not surprising to me,</p> <p>21 considering it's around in pure form.</p> <p>22 Q. It's around in pure form?</p> <p>23 Expand on what you mean by that.</p> <p>24 A. In pure form, to me, you</p>																		

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1 produce it by a company such as Sigma for
2 research purposes. In unpure form, NDMA is
3 produced in many other scenarios, including
4 beer, bacon and so on.

5 Q. Do you know what it is used for
6 as far as research purposes, how NDMA is used
7 for research?

8 A. As a genetic toxicologist, I'm
9 aware that it's used for -- it can be used
10 for research if people are looking at the
11 genetic toxicology profile of NDMA.

12 Q. Are you aware that it is used
13 as a cancer initiator in laboratory animals?

14 A. I'm aware that there's studies
15 that show that cancer at certain doses is
16 produced in the laboratory animals.

17 Q. And similarly for NDEA, are you
18 aware that NDEA is used in research purposes
19 to initiate cancer in laboratory animals?

20 A. I'm aware that NDEA has been
21 used to show dose-response information using
22 the cancer bioassay as evidenced in my report
23 as well.

24 Q. And when you say has been --

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1 NDEA has been used to show dose-response
2 information in the cancer bioassay, that
3 would be NDMA -- NDEA has been used in
4 research to cause cancer in laboratory
5 animals, correct?

6 A. Yes, as evidenced -- yes, I did
7 say in the Peto study that shows NDEA induces
8 cancer at certain concentrations in the
9 rodent cancer bioassay.

10 Q. Thank you.

11 MS. BOGDAN: If we could please
12 pull up IRIS Nitrosodimethylamine;
13 CASRN 62-75-9.

14 (Whereupon, Deposition Exhibit
15 Johnson-25, IRIS Chemical Assessment
16 Summary, N-Nitrosodimethylamine;
17 CASRN 62-75-9, was marked for
18 identification.)

19 A. It would appear as Exhibit 25?

20 MS. BOGDAN: It should.

21 THE WITNESS: Thank you.

22 TRIAL TECHNICIAN: Is that the
23 correct document?

24 MS. BOGDAN: Yes, it is.

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1 TRIAL TECHNICIAN: Thank you.

2 THE WITNESS: Not yet.

3 Apologies. It's appeared. It's
4 loading. It's on my screen.

5 BY MS. BOGDAN:

6 Q. And, Dr. Johnson, have you seen
7 this exhibit before?

8 (Interruption off the record.)

9 MS. BOGDAN: I'm not sure
10 what's going on in the room, but
11 it's --

12 MS. LOCKARD: We got a prank
13 call. We'll proceed. Let's proceed.

14 THE WITNESS: I remember the
15 question. I can answer the question.

16 A. I cannot recall seeing this
17 document.

18 BY MS. BOGDAN:

19 Q. Are you familiar with the
20 Integrated Risk Information System for the
21 U.S. Environmental Protection Agency?

22 A. I am aware of the Integrated
23 Risk Information System, IRIS, of the EPA.

24 Q. Okay. If you could please turn

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1 to the second page of the document.

2 A. I'm on the second page of the
3 document.

4 Q. You said you have not seen this
5 before?

6 A. I can't recall -- (audio
7 malfunction) --

8 (Clarification requested by the
9 stenographer.)

10 A. I cannot recall seeing this
11 before.

12 BY MS. BOGDAN:

13 Q. Does the EPA use a linear
14 low-dose extrapolation for risk assessment
15 related to NDMA?

16 MS. LOCKARD: Objection, form,
17 speculation.

18 A. I cannot recall their
19 assessment.

20 BY MS. BOGDAN:

21 Q. Directing your attention to the
22 second section, Carcinogenicity Assessment
23 for Lifetime Exposure.

24 Do you see that section?

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1 A. I see that section.
 2 Q. And do you see the sentence in
 3 the paragraph that begins: The slope factor
 4 is the result of application of a low-dose
 5 extrapolation procedure?
 6 A. I do see that.
 7 Q. Does it appear from this
 8 document that the USEPA uses a linear
 9 low-dose extrapolation method for assessing
 10 the carcinogenicity of NDMA?
 11 MS. LOCKARD: Objection, form,
 12 speculation.
 13 A. I do see that that's presented
 14 in this document from the EPA, and it does
 15 not change my opinion as presented in my
 16 report.
 17 BY MS. BOGDAN:
 18 Q. I didn't ask -- I was asking if
 19 the U.S. Environmental Protection Agency uses
 20 a low-dose linear extrapolation to determine
 21 the carcinogenicity of NDMA and whether this
 22 document indicates that.
 23 Do you see that presented in
 24 this document?

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1 MS. LOCKARD: Objection, vague.
 2 A. I see in this document they use
 3 a slope factor and a linear low-dose
 4 assessment to calculate these different
 5 cancer risks, and it does not change my
 6 opinion in my report.
 7 BY MS. BOGDAN:
 8 Q. Going down a little further on
 9 the same page, do you see the
 10 Weight-of-Evidence Characterization section?
 11 A. Yes, I do.
 12 Q. And how is NDMA classified?
 13 A. It is classified B2, probable
 14 human carcinogen.
 15 Q. Thank you.
 16 A. In this document.
 17 MS. BOGDAN: If we could please
 18 pull the next exhibit, which is
 19 N-nitrosodiethylamine. Again, an
 20 Integrated Risk Information System,
 21 IRS [sic] document, CASRN 55-18-5.
 22 (Whereupon, Deposition Exhibit
 23 Johnson-26, IRIS Chemical Assessment
 24 Summary, N-Nitrosodiethylamine;

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1 CASRN 55-18-5, was marked for
 2 identification.)
 3 THE WITNESS: Firstly, I would
 4 like to, just on record, record the
 5 date of the document you've showed me.
 6 It looks to be 1987. Okay.
 7 MS. BOGDAN: As far as the last
 8 revision, yes.
 9 THE WITNESS: Yes.
 10 MS. BOGDAN: Has the next
 11 exhibit loaded?
 12 THE WITNESS: Would this be 26?
 13 MS. BOGDAN: I believe so.
 14 THE WITNESS: It has loaded.
 15 I've clicked on it. It's in front of
 16 me.
 17 BY MS. BOGDAN:
 18 Q. All right. And this is a
 19 similar Integrated Risk Information System
 20 document, but this one pertains to
 21 N-nitrosodiethylamine.
 22 Do you see that at the top?
 23 A. I do see that from this 1987
 24 document.

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1 Q. I'm directing your attention,
 2 again, to Section II on page 2, which is the
 3 Carcinogenicity Assessment for Lifetime
 4 Exposure.
 5 A. I can see that.
 6 Q. And similarly in that
 7 descriptive paragraph, it reads: The slope
 8 factor is the result of application of a
 9 low-dose extrapolation procedure.
 10 Do you see that?
 11 A. I do see that.
 12 Q. Does this document indicate
 13 that the EPA uses a low-dose linear
 14 extrapolation to determine the
 15 carcinogenicity assessment for NDEA?
 16 MS. LOCKARD: Objection, form,
 17 speculation.
 18 A. I agree that they used this
 19 linear back-extrapolation for NDEA in 1987
 20 from the EPA, prior to the Peto study.
 21 BY MS. BOGDAN:
 22 Q. And directing your attention to
 23 Section II.A, Evidence For Human
 24 Carcinogenicity and the Weight-of-Evidence

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1 Characterization. How is NDEA classified in
 2 this document?

3 A. NDEA is classified in this
 4 document with this hazard classification of
 5 being a B2, probable human carcinogen, in
 6 1987.

7 Q. And you say in 1987. Have you
 8 checked the Integrated Risk Information
 9 System to see if or how NDMA and NDEA are
 10 currently classified?

11 A. I have not. I'm commenting on
 12 what I'm seeing here.

13 Q. And when you say commenting,
 14 you're commenting regarding the last revision
 15 that's noted on page 1 of the document?

16 A. With regards to the date, was
 17 that the question?

18 Q. Yes.

19 A. This is -- yes, I'm commenting
 20 that this date presented here is the correct
 21 date where this is presented first online,
 22 31st of the 1st, 1987, is the comment that
 23 I'm making on this date.

24 Q. And then it also indicates

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1 right in that -- under that first online date
 2 that the last time it was revised was
 3 January 31st, 1987.

4 Do you see that over on the
 5 right side of the page?

6 A. I see that on the right-hand
 7 side of the page.

8 Q. Do you have any reason to
 9 believe that this is not the current
 10 assessment of the Integrated Risk Information
 11 System with regard to NDEA?

12 A. I am not aware, and I'm
 13 commenting on the document put in front of me
 14 here.

15 Q. Thank you.

16 MS. BOGDAN: If we could pull
 17 up the next exhibit, which is Control
 18 of Nitrosamine Impurities in Human
 19 Drugs.
 20 (Whereupon, Deposition Exhibit
 21 Johnson-27, Control of Nitrosamine
 22 Impurities in Human Drugs Guidance for
 23 Industry, was marked for
 24 identification.)

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1 THE STENOGRAPHER: Exhibit 27.
 2 THE WITNESS: Not there yet for
 3 me.
 4 It's there for me. I can see
 5 it on my screen.

6 BY MS. BOGDAN:

7 Q. Okay. Are you familiar with
 8 this document?

9 A. I am not aware. I cannot
 10 recall.

11 Q. And when is this document
 12 dated?

13 A. This document on the first page
 14 is dated February 2021.

15 Q. Did you research the guidance
 16 that the U.S. Department of Health and Human
 17 Services, the Food and Drug Administration,
 18 otherwise known as the FDA?

19 A. I did research the numerous
 20 documents on this evolving case from the FDA.

21 Q. And is this one of the
 22 documents that you discovered and reviewed?

23 A. I think so.

24 Q. But you're not certain of that?

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1 A. I have read a huge amount of
 2 FDA documents on this topic, and I think -- I
 3 think that this is one of them.

4 Q. If we could go to page 5. And
 5 it may not be page 5 of the PDF, but be
 6 page 5 of the document as numbered.

7 A. Could you indicate the first
 8 line of that page, just so I can find it,
 9 please.

10 Q. It should begin "Nitrosamine
 11 compounds are."

12 A. Excellent. I'm on the page.

13 Q. Would you please read the first
 14 sentence.

15 A. Nitrosamine compounds are
 16 potent genotoxic agents in several animal
 17 species and some are classified as probable
 18 or possible human carcinogens by the
 19 International Agency for Research on Cancer,
 20 IARC. And then citation 18.

21 Q. Do you know how many animal
 22 species have been shown to develop cancer
 23 when administered NDMA?

24 A. In robust studies, as would be

<p style="text-align: right;">Page 340</p> <p>1 used for my risk assessment that would be 2 available on the cancer potency database, 3 there was rat, mice and rhesus monkeys, and 4 those were the robust ones in line with OECD 5 guidelines that could be used for this risk 6 assessment. And those would be the ones I 7 would comment on. 8 Q. Did you look for other animal 9 species other than the rat, mice and I 10 believe you said rhesus monkeys? 11 A. I looked at those datasets on 12 the cancer potency database, and during one 13 of my readings of another expert witness' 14 deposition, there was discussion -- actually, 15 in their expert report, I think, they 16 discussed in depth multiple animals, multiple 17 animal studies where they stated cancer had 18 been shown, and in that regard, I looked into 19 those and did an assessment of study design, 20 the date tested, route of administration, 21 seeing if they were correct, and I did not 22 confirm that those multiples suggested by -- 23 in that report showed convincingly that there 24 was cancer, particularly cancer related to</p>	<p style="text-align: right;">Page 342</p> <p>1 Q. And the Peto study studied both 2 NDMA and NDEA, correct? 3 A. Both the NDMA and NDEA in the 4 Peto study showed a dose response in the 5 cancer bioassay for both substances. 6 Q. And when you say dose response, 7 does that mean that the more of the substance 8 that was administered, either NDMA or NDEA, 9 the more cancer was seen, the more incidence 10 of cancer was seen? 11 A. With a dose response at certain 12 levels in a nonlinear manner, I did see an 13 increase in cancer with increasing dose at 14 certain concentrations, but I did not see 15 that in a linear fashion. 16 BY MS. BOGDAN: 17 Q. Directing your attention back 18 to the exhibit, do you see the sentence that 19 begins in that first paragraph "The guidance 20 recommends"? 21 A. Are we on the same page, 22 starting "Nitrosamine compounds"? 23 Q. Yep. It's the third sentence 24 in the first paragraph. It begins "The</p>
<p style="text-align: right;">Page 341</p> <p>1 the doses we're seeing here. 2 So that would be my comment on 3 those. 4 Q. In your research, did you note 5 or find any study that showed any type of 6 animal was resistant to developing cancer 7 from NDMA when administered NDMA? 8 A. From my understanding of your 9 term "resistant," I would talk about dose 10 where a resistance to the substances would be 11 through DNA repair, specifically MGMT. So if 12 there were doses where cancer was not seen, 13 such as in the Peto study, then that would 14 support resistance at certain concentrations 15 of NDMA and NDEA. 16 So I was aware of that. 17 Q. And are you aware of any study 18 where NDMA was administered at high doses 19 where the animal was resistant or did not 20 develop cancer? 21 A. In high doses, such as the Peto 22 study, with increased dose, there were 23 increased levels of cancer in that cancer 24 bioassay study, for example.</p>	<p style="text-align: right;">Page 343</p> <p>1 guidance recommends"? 2 A. Excellent. I see that. 3 Q. Okay. Could you please read 4 that sentence? 5 A. The sentence reads: The 6 guidance recommends control of any known 7 mutagenic carcinogen such as 8 nitroso-compounds, at or below a level such 9 that there would be a negligible human cancer 10 risk associated with the exposure to 11 potentially mutagenic impurities. 12 Q. And you agree that there should 13 be control of any known mutagenic carcinogens 14 such as nitroso compounds at or below a level 15 such that there would be a negligible human 16 cancer risk? 17 MS. LOCKARD: Objection, form. 18 A. I agree with this statement. I 19 also point towards another option within the 20 M7 guidance to calculate and to abide to this 21 sentence in a different way; if we have an 22 understanding of DNA repair, then we can use 23 the PDE approach. 24 So I abide to this, agree that</p>

<p style="text-align: right;">Page 344</p> <p>1 this is what we could do, and my approach is 2 also in support of this approach. And I can 3 justify it through the mutagenic mechanism of 4 action for dose response, and the threshold 5 mechanism being DNA repair. And this is 6 entirely in line with this same document as 7 cited here, M7. 8 Q. However, your approach is not 9 the one that has been adopted by the FDA, 10 correct, in establishing the limits for NDMA 11 and NDEA? 12 A. At the current time, that is 13 correct. 14 Q. If we could move to page 10 of 15 the document, please. 16 A. I'm on page 10. There's a 17 table -- Table 1 at the top. I'm on that 18 page, Acceptable Intake Limits; is that 19 correct? 20 Q. Yes, it is. I think for the 21 people on Zoom, we need to have it moved up a 22 little bit. 23 And do you see Acceptable 24 Intake Limits on the top of this page?</p>	<p style="text-align: right;">Page 346</p> <p>1 Q. And that's the acceptable 2 intake limit established by the FDA, correct? 3 A. That is the acceptable intake 4 limit as established by the FDA using this 5 calculation for 70 years of exposure to 6 1-in-100,000 cancer risk, according to this 7 legend. 8 Q. And if we could please move to 9 Appendix B of this exhibit. 10 THE STENOGRAPHER: B, bravo? 11 MS. BOGDAN: Yeah, it would be 12 the very last page. 13 THE WITNESS: Very last page. 14 What number would that be? 15 MS. BOGDAN: It actually has a 16 number 1 on it, but it's the very last 17 page of the PDF. 18 THE WITNESS: So top is 19 Contains Nonbinding Recommendations, 20 Appendix B, FDA Determination. Is 21 that the one? 22 MS. BOGDAN: Yes. 23 THE WITNESS: Excellent, I'm on 24 it, thank you.</p>
<p style="text-align: right;">Page 345</p> <p>1 A. I do see that. 2 Q. Okay. And then there's a table 3 that has the acceptable limits for NDMA, NDEA 4 and some other N-nitroso compounds? 5 A. I do see that. 6 Q. Okay. And what are the 7 acceptable intake limits according to the FDA 8 for NDMA? 9 A. Well, NDMA, the FDA calculated 10 limits using a TD50 linear back-extrapolation 11 to 1 in 100,000 people based on this animal 12 study is 96 nanograms per day. 13 Q. And that's reflected in 14 Table 1? 15 A. That is reflected in Table 1. 16 It's the top row. 17 Q. And what is the acceptable 18 intake limit established by the FDA for NDEA? 19 A. For NDEA, using a linear 20 back-extrapolation from the harmonic mean of 21 the TD50 to 1-in-100,000 cancer risk after 22 70 years of exposure, same as with NDMA, 23 after 70 years of exposure, the acceptable 24 intake is 26.5 nanograms per day.</p>	<p style="text-align: right;">Page 347</p> <p>1 BY MS. BOGDAN: 2 Q. And does this appendix set 3 forth how the FDA calculated the acceptable 4 intake limit for NDMA? 5 A. I have read that first 6 paragraph in full and see that this explains 7 how the calculation for the acceptable intake 8 based on the linear back-extrapolation to 9 calculate the risk of 1 in 100,000 people for 10 lifetime exposure in a 50-kilogram human is 11 how they calculated those presented 12 acceptable intakes. 13 Q. That describes generally how 14 they go about doing their calculation, 15 correct? 16 MS. LOCKARD: Objection, form, 17 vague. 18 A. That's generally how you 19 calculate, and that's how they calculated 20 this very conservative and imprecise 21 acceptable intake as presented in this 22 document. 23 BY MS. BOGDAN: 24 Q. And then under that first</p>

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1 paragraph, they actually give NDMA as an
2 example?
3 A. It looks that way.
4 Q. Okay. And they show in that
5 paragraph how they derived the 96 nanograms
6 per day, correct?
7 A. They do. They assumed no
8 established threshold mechanism, so no
9 consideration of DNA repair was one of their
10 assumptions. They assumed the level of risk
11 would be 1 in 100,000, considering the
12 background level of this type of cancer would
13 be, say, 1 in 200.
14 So those assumptions were made,
15 and the calculation did -- was used in order
16 to generate their acceptable intake values,
17 as you've just suggested.
18 Q. And to do their calculations,
19 the FDA assumed there is no threshold,
20 correct?
21 A. They -- yeah, as stated here,
22 with no established threshold mechanism, that
23 was one of their assumptions. And this is
24 one of the assumptions that I've been working

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1 on, and this is one of the assumptions that
2 I've just been commissioned by the European
3 Medicines Agency to look into for a wider
4 breadth of nitrosamines as well.
5 So I'm a leading expert in this
6 area of threshold mechanisms, and the EMA
7 have commissioned me to look into this
8 further. So I know a lot about this topic,
9 and that was the assumption. There was no
10 established threshold mechanism. And that
11 led, instead of the PDE, to use the
12 acceptable intake. That's why I mentioned
13 that assumption.
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Page 358

Page 357

Page 359

Page 362

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Category	Percentage
1	95%
2	40%
3	65%
4	75%
5	90%
6	70%
7	70%
8	95%
9	85%
10	75%
11	90%
12	65%
13	85%
14	95%
15	60%
16	85%
17	30%
18	75%
19	95%
20	30%
21	85%
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13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 Q. Did you cite that MNU paper in
21 your report?
22 A. I'd have to look.
23 Q. Yes, please.
24 And who is the first author on

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1 that paper?
2 A. Adam Thomas, T-H-O-M-A-S.
3 Q. When you say Adam, is that the
4 first name and Thomas the last name? Or is
5 Thomas the first name and Adam the last name?
6 A. Thomas is the last name, and
7 Adam is the first name. It's a strange name.
8 Thank you. Sorry.
9 Q. No.
10 If you can't find it easily,
11 what year was it published approximately?
12 A. It would be easier to find in
13 my CV. Could I have time to look for it in
14 my CV?
15 Q. Sure, if you can find it in
16 your CV.
17 MS. LOCKARD: Can I suggest
18 that he look at a footnote, or does
19 that violate your rule? I don't want
20 to impede, but if it would help, I
21 could -- I have an electronic
22 searchable copy, so...
23 THE WITNESS: Sorry about this.
24 ///

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1 BY MS. BOGDAN:
2 Q. On page 7 of your CV, where you
3 have your publications --
4 A. Yep, I think -- I think, not
5 certain, I think it's the 2013, Influence of
6 DNA Repair on Nonlinear Dose Responses for
7 Mutation, ToxSci. I think that's the one.
8 Q. Okay. Thank you.
9 And what is the amount that GSK
10 is paying to fund this research project being
11 done by your postdoc?
12 A. At an estimate, a postdoc plus
13 full economic costing to cover those aspects
14 I think at 100%. So his wage, 100% to cover
15 all lab space, all that kind of stuff, and
16 lab consumables.
17 I think the total is
18 approximately 100,000.
19 Q. Are there any other research
20 projects that are currently underway at
21 Swansea University that would pertain to the
22 issues in this litigation?
23 A. There would be no additional
24 lab work projects associated with

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1 nitrosamines, but I have an ongoing interest
2 in this work and will continue to
3 independently research this topic in a
4 scientific way.
5 And that would be under
6 university funding and my time allocated to
7 carry out independent research.
8 Q. And as an assistant professor,
9 is there a certain amount of time that you
10 are allowed to engage in independent research
11 each year?
12 A. For the record, it's an
13 associate professor.
14 Q. Oh.
15 A. So that's the one -- assistant
16 is the one below associate in the U.S. So
17 I'm associate professor.
18 So the ballpark figure for an
19 academic with ten years such as myself in my
20 university, the ballpark figure is 40%
21 research, 40% teaching, 20% administration.
22 And then as an academic, you end up doing
23 more than that, but that's -- those are the
24 numbers.

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1 Q. Okay.
2 THE WITNESS: Apologies, can I
3 have a rest break soon?
4 MS. BOGDAN: Sure.
5 THE WITNESS: Is it a good
6 time?
7 MS. BOGDAN: Yeah, we can take
8 one right now if you want to do a
9 quick five-minute break, since I've
10 not started another document.
11 THE WITNESS: Thank you.
12 THE VIDEOGRAPHER: Off the
13 record. The time is 10:16 a.m.
14 (Recess taken, 10:16 a.m. to
15 10:23 a.m. BST)
16 THE VIDEOGRAPHER: We're back
17 on the record. The time is 10:23 a.m.
18 BY MS. BOGDAN:
19 Q. Are there any other ongoing
20 research projects that you're consulting on
21 that are not being done at Swansea University
22 but somewhere else, pertaining to
23 nitrosamines?
24 A. Oh. No, there are not.

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1 Q. Has GSK funded postdoc work in
2 your department in the past?
3 A. Not that I'm aware of.
4 Q. And how was that particular
5 postdoc student selected to do work on the
6 project?
7 A. He was selected by myself, and
8 it was an open call for that project for
9 others to apply. He was selected based on
10 his expertise. He's an expert in genetic
11 toxicology. He's carried out research in my
12 laboratory previously. I think he even -- he
13 did carry his Ph.D. out with me as well.
14 I've worked with him for many
15 years. He's an expert in genetic toxicology.
16 He's a very, very hard worker. I have a lot
17 of time for him. He's perfect for the job,
18 he got the job.
19 Q. When you say an open call, does
20 that mean that there was like a posting for
21 the position?
22 A. Yes. Ah. Apologies, no.
23 Apologies. I think in this instance when the
24 person is named in the grant, it doesn't have

Page 370

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7 MS. BOGDAN: Could we please
8 pull up the next exhibit, which is the
9 February 14th, 2019 EMA assessment
10 report.
11 (Whereupon, Deposition Exhibit
12 Johnson-28, 2/14/19 EMA Assessment
13 Report, was marked for
14 identification.)
15 THE STENOGRAPHER: Exhibit 28.
16 BY MS. BOGDAN:
17 Q. And please let me know once
18 it's loaded.
19 A. I will. Apologies for the
20 slow -- we're on Wi-Fi, not wired. It's
21 popped up. It's loading. There we go. I
22 can see it now. I can see it.
23 Q. Okay. Have you seen this
24 document before?

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1 A. I think I have seen this
 2 document, and I've seen many documents from
 3 EMA.
 4 Q. And this document was issued
 5 February 14th, 2019 from the face of the
 6 document there at the top?
 7 A. According to the details on
 8 this document, yes, 14th of February 2019. I
 9 can see that.
 10 Q. I'm going to direct your
 11 attention to page 17.
 12 A. I'm almost there.
 13 MS. LOCKARD: Page 17 of the
 14 PDF or the --
 15 MS. BOGDAN: Page 17 of 41 as
 16 numbered on the bottom right-hand side
 17 of the document.
 18 THE WITNESS: I have found it,
 19 and the first word is-- the first two
 20 words are "mean values."
 21 MS. BOGDAN: Correct.
 22 THE WITNESS: I can see that.
 23 BY MS. BOGDAN:
 24 Q. Referring you to Table 3.

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1 A. Referred.
 2 Q. Yeah. Do you see the -- and
 3 what is that table titled?
 4 A. Highest NDMA mean values found
 5 in API and FP.
 6 Q. And do you see the values for
 7 valsartan API by ZH?
 8 A. I see those, yes. Valsartan
 9 API by ZH, valsartan FP containing API by ZH.
 10 I see those.
 11 Q. Okay. What is the value
 12 indicated under Highest there?
 13 A. For API, Highest states 240. I
 14 think that -- is that the microgram value or
 15 is that the ppm? Can you correct that for
 16 me, just as you may have seen this before?
 17 Q. It -- it indicates on the top
 18 of the column headings, it says NDMA ppm,
 19 which is also micrograms per gram.
 20 Do you see that on the top?
 21 A. I see that on the top. Thank
 22 you for that clarity.
 23 So those values, my -- I prefer
 24 working in micrograms per gram -- the highest

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1 in the API is 240.1, and in the FP, it's
 2 97.4.
 3 Q. So working with the highest
 4 number for the valsartan API of 240.1, what
 5 would be the total amount of NDMA in a
 6 320-milligram tablet?
 7 A. I do not know the answer
 8 because this is the API, and I'm not an
 9 expert in formulation for the final product.
 10 So that would be an estimation and would not
 11 be precise.
 12 Q. Do you know how to take the ppm
 13 in valsartan API and convert it to the amount
 14 of NDMA that would be in a tablet if that API
 15 was used?
 16 A. I do not know that calculation
 17 that you've just stated. My focus has always
 18 been on the finished product, to which we
 19 have these numbers that we can more precisely
 20 refer to.
 21 Q. With regard to the highest NDMA
 22 ppm found in the finished product on this
 23 chart, what is that number?
 24 A. That is 97.4 microgram per

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1 gram.
 2 Q. If that valsartan finished
 3 product was a 320-milligram pill, can you
 4 tell me how much NDMA would be in that pill
 5 based on the 97.4 NDMA ppm?
 6 MS. LOCKARD: Objection, asked
 7 and answered, speculation.
 8 A. From this table, without a
 9 calculator, I could not do this for you.
 10 BY MS. BOGDAN:
 11 Q. How would you calculate the
 12 amount of NDMA in a 320-milligram tablet
 13 using the highest NDMA ppm value shown for
 14 the valsartan finished product in the chart?
 15 A. You would correct it -- so
 16 instead of being per gram, you correct it to
 17 320 milligrams or .32 grams, and you correct
 18 it that way.
 19 Q. And other than that correction,
 20 would you do any other calculation with that
 21 number?
 22 A. As far as I'm aware, that would
 23 not be the case. But I did not do the
 24 calculation you're suggesting. As stated in

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1 my report, I'm going with the finished
2 product as stated in the metrics provided in
3 my report.
4 Q. Directing your attention
5 further down in this document to the bullet
6 point that begins with 240.1 ppm.
7 A. I can see that.
8 Q. Could you please read that --
9 or those two sentences?
10 A. Two sentences. The one
11 starting 240.1, those two sentences?
12 So: 240.1 ppm as the highest
13 NDMA contamination found in ZH API batches,
14 as communicated by ZH. This would result in
15 76.8 microgram per day in a 320-milligram
16 valsartan tablet.
17 Q. And how many nanograms would
18 76.8 micrograms be?
19 A. Nanograms. So you would
20 multiply that by a thousand.
21 Q. Okay. So how many nanograms
22 would 76.8 micrograms be?
23 A. It would be that value
24 multiplied by a thousand.

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1 Q. Which would be 76,800
2 nanograms?
3 A. Yes.
4 Q. Did you take values such as
5 76,800 nanograms per tablet into
6 consideration when forming your opinions in
7 this case?
8 A. My opinions in this case can be
9 explained if we look at my report where the
10 PDE is calculated, and the PDE upper bounds
11 are calculated. My opinions can lie to those
12 calculations.
13 I adjusted this to the more
14 realistic average population of 100 kilograms
15 for the individuals here. As I would see
16 from average population size, 100 would be
17 closer to the population average, in this
18 case. So I did that calculation in my
19 report.
20 And also with the smaller
21 population, the adjustment factors could be
22 discussed as going from 50 -- from 500 down
23 to 50 to calculate that PDE and the PDE
24 confidence interval for both 50 and

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1 100 kilograms.
2 And from that, with this also
3 recollection and understanding that reducing
4 that uncertainty factor could lead to a
5 tenfold increase in -- order of magnitude
6 increase in the PDEs presented in my report,
7 I could consider that this individual exposed
8 to this would also not have an increased risk
9 of cancer, according to those calculations
10 I've just explained.
11 So this was not a value
12 included in my report, but seeing this value
13 here, in line with my explanation, I would
14 not see this individual as having an
15 increased risk of cancer, through that
16 explanation.
17 Q. My question was -- and let me
18 ask it again -- is if in your report you
19 referenced values and considered them that
20 are in the range of 76,800 nanograms per
21 tablet.
22 A. The -- this document -- is this
23 the EMA one? So this EMA document would
24 relate to the European exposure limits and

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1 European case, and the numbers within my
2 report relate to the FDA values covering the
3 United States. So far that reason, this
4 value was -- is not included in my report.
5 Q. Did you look to the values for
6 the NDMA found in the ZHP product that made
7 the U.S.?
8 A. Can you repeat? I didn't -- I
9 didn't hear if it was the API or the finished
10 product. Apologies.
11 Q. Did you look to determine the
12 values for the ZHP API that was sold in the
13 U.S.?
14 A. I looked at the finished
15 product and not the API because the
16 conversion from API to finished product, from
17 my understanding, is -- could potentially be
18 variable, and the extrapolation I would not
19 be comfortable with.
20 So my work would always be
21 linked to the finished product, which I think
22 is a more reliable metric here for the
23 assessment.
24 Q. Did you look in the internal

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1 documents of ZHP to find the highest level of
2 NDMA that was found in the finished tablet?
3 A. I have seen these documents and
4 have looked at that information, yes.
5 Q. And what was the highest level
6 of NDMA that you found for a ZHP finished
7 tablet as part of your work on this case?
8 A. I cannot recall the exact
9 number, but finding out that number did not
10 change my opinion as presented in my report,
11 that those individuals had increased risk of
12 cancer. It did not change it. But I can't
13 recall the exact number.
14 Q. Can you -- do you recall the
15 general level of that number, meaning was it
16 20 micrograms, 30 micrograms?
17 MS. LOCKARD: Objection, vague,
18 asked and answered.
19 A. I do not know, as previously
20 stated.
21 BY MS. BOGDAN:
22 Q. Did you report that highest
23 level of NDMA contamination that you found in
24 your work on this case?

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1 A. In my work, all of the
2 assumptions within the stated report relate
3 to that FDA table, and then upon reflection
4 of this additional information, I still do
5 not change the conclusion that those
6 individuals have an increased risk of cancer.
7 MS. BOGDAN: We can take this
8 exhibit down, please.
9 If we could please pull up the
10 document entitled Calculation of AI
11 Associated with Acceptable Excess
12 Cancer Risk.
13 (Whereupon, Deposition Exhibit
14 Johnson-29, Demonstrative, Calculation
15 of AI associated with acceptable
16 excess cancer risk - ICH M7, was
17 marked for identification.)
18 THE STENOGRAPHER: Exhibit 29.
19 THE WITNESS: It's not there
20 with me yet. Still not there. Maybe
21 it's a large file.
22 TRIAL TECHNICIAN: I'm just
23 waiting on the number.
24 THE WITNESS: Still not there.

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1 TRIAL TECHNICIAN: Rosemarie, I
2 think we're having trouble locating
3 that. What is the -- what's the name
4 of it again? Does it have a -- like a
5 C1 number in front of it?
6 MS. BOGDAN: It's a PowerPoint
7 slide entitled Calculation of AI
8 Associated With Acceptable Cancer
9 Risk.
10 TRIAL TECHNICIAN: I think
11 we've got it.
12 MS. BOGDAN: No, not that one.
13 TRIAL TECHNICIAN: Not that
14 one.
15 MS. BOGDAN: But that is one --
16 there we go.
17 TRIAL TECHNICIAN: All right.
18 Bear with me one moment. You should
19 see that now.
20 THE WITNESS: Excellent. It is
21 appearing. I'm loading it. I can see
22 it.
23 BY MS. BOGDAN:
24 Q. Okay. Do you recognize this

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1 PowerPoint slide?
2 A. I recognize this PowerPoint
3 slide as one that I borrowed from a
4 presentation from Roland Frotschl from -- I
5 think it was a GUM meeting, German
6 mutagenicity meeting, yes.
7 Q. And what does -- does this
8 slide show the calculation of the acceptable
9 intake risk that was used by the FDA and the
10 EMA to calculate the 96-nanogram-per-day
11 acceptable intake limit for NDMA?
12 A. Yes, this is a slide from
13 Roland where he shows that. And in my
14 presentations, I show this as -- that
15 acceptable intake as one approach, and then
16 always following on or show the other option
17 within the ICH guidance for the PDE. So just
18 the context as well as the information.
19 Q. And this is also the
20 methodology that was used by the FDA and EMA
21 to calculate the acceptable intake limit for
22 NDEA?
23 A. The previous document that you
24 showed me, potentially from FDA which showed

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1 the calculation, is expanded upon in this
 2 slide to make it more exploratory -- no, more
 3 explanatory and easier to discuss the
 4 linear -- drawing a straight line back from
 5 the TD50 to 1-in-100 risk. It's actually
 6 1-in-100 risk in animals. There's no
 7 extrapolation factor to humans, and so on.
 8 So I present it and critique it as we go
 9 through.

10 Q. My question was: Was this
 11 methodology that's shown in this slide also
 12 used to calculate the NDEA acceptable intake
 13 risk by the FDA and the EMA?

14 A. This calculation is also used
 15 by those regulatory bodies to calculate
 16 acceptable intake for NDEA, yes.

17 Q. Okay. And the -- what is the
 18 acceptable daily intake for NDEA as
 19 determined by the EMA and the FDA?

20 A. As you've showed me previously
 21 multiple times, that value is 26.5 microgram
 22 per day.

23 Q. Now, referring to this slide,
 24 can you read the first sentence on the slide,

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1 please.

2 A. The first sentence of the
 3 slide, according to Roland Frotschl's slide
 4 here, is: Daily intake for lifetime,
 5 70 years, of a mutagenic carcinogen that is
 6 considered to be associated with an excess
 7 cancer risk of no more than 1 in 100,000 is
 8 considered acceptable -- or consider
 9 acceptable -- must be a typo -- considered
 10 acceptable according to ICH M7.

11 And then in further slides, I
 12 also say acceptable according to ICH M7 is
 13 the PDE approach for context.

14 Q. However, the approach that is
 15 shown on this slide, which is followed by the
 16 FDA, is acceptable according to ICH M7,
 17 correct?

18 A. That is correct. This approach
 19 is also acceptable under ICH M7.

20 Q. And do you notice the words in
 21 this sentence "excess cancer risk"?

22 A. I do note those, yes.

23 Q. Okay. And when doing this
 24 calculation, it is the intent to limit the

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1 excess cancer risk to no more than 1 in
 2 100,000, correct?

3 A. As stated here, that is
 4 correct. And that's also the terminology you
 5 can use with the PDE calculation as put
 6 forward in my document.

7 Q. And when the FDA is making the
 8 determination with regard to the acceptable
 9 intake, it is concerned with preventing
 10 excess cancer, correct?

11 A. Correct, according to this
 12 slide.

13 Q. And when they refer to excess
 14 cancer risk, they are concerned with
 15 preventing additional cases of cancer
 16 associated with taking medications with NDMA
 17 or NDEA in them, correct?

18 A. That's part of the explanation.
 19 And an additional part would be excess above
 20 the background rate in humans. And the
 21 actual background rate of humans would be,
 22 say, 1 in 2 for general cancer or, say, 1 in
 23 200 for liver cancer. So 1 in 2 for whole
 24 cancer, in this term, would actually be

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1 50,000 out of 100,000. That's the
 2 background.

3 So it's inaccurate in that way,
 4 but yes, according to your statement, this
 5 does show excess cancer risk is what we're --
 6 what we're assessing for with the AI in NDMA
 7 and NDEA.

8 Q. And do you agree that lowering
 9 one's exposure to carcinogens lessens their
 10 risk of cancer?

11 A. It depends on the dose. If
 12 you're already at a dose where that compound
 13 is not causing any cancer, then it makes no
 14 difference, really, if there's a lower level
 15 of that compound.

16 Q. So it's your testimony that
 17 lowering a person's exposure to carcinogens
 18 does not necessarily lessen their risks of
 19 developing cancer?

20 A. I would state that if the
 21 compound is at a level that is not inducing
 22 any cancer and you reduce that level of
 23 compound even further, then those individuals
 24 would not be -- they would also not be at

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1 increased risk of cancer.
 2 Q. And that's true even if the
 3 compound is a known genotoxic mutagen?
 4 A. If the known genotoxic mutagen
 5 is not causing any mutation or cancer at the
 6 concentration of exposure, and that's
 7 reduced, then, again, there would not be an
 8 increased level of mutation.
 9 MS. BOGDAN: Could we please
 10 pull up the next exhibit, which is the
 11 Calculation of Excess Risk for Less
 12 Than Lifetime Exposure, M7 TD50
 13 Linear.
 14 (Whereupon, Deposition Exhibit
 15 Johnson-30, Demonstrative, Calculation
 16 of excess risk for less than lifetime
 17 exposure, NDMA average in FP, was
 18 marked for identification.)
 19 THE STENOGRAPHER: Exhibit 30.
 20 THE WITNESS: Can I ask, will
 21 this be a long one? I need another
 22 short break at some time soon.
 23 MS. BOGDAN: If you want to
 24 take just a few minutes, we can do

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1 that. I don't want you to be
 2 uncomfortable.
 3 THE WITNESS: That's very much
 4 appreciated.
 5 MS. BOGDAN: Okay.
 6 THE VIDEOGRAPHER: Going off
 7 the record. The time is 10:54 a.m.
 8 (Recess taken, 10:54 a.m. to
 9 10:57 a.m. BST)
 10 THE VIDEOGRAPHER: Back on the
 11 record. The time is 10:57 a.m.
 12 BY MS. BOGDAN:
 13 Q. Can you see Exhibit 30?
 14 A. I can see Exhibit 30.
 15 Q. And do you recognize this
 16 slide?
 17 A. I recognize this slide as
 18 another part of Roland Frotschl's slide set
 19 from that GUM meeting, which I then used to
 20 explain how the regulatory bodies calculated
 21 these values, and then later critiqued these
 22 approaches in this presentation.
 23 So yes, I do know this slide.
 24 Q. But this slide explains how the

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1 FDA and the EMA calculated these acceptable
 2 intake limits, correct?
 3 A. It's correct for EMA, but I'm
 4 not comfortable for FDA, where the years
 5 taken for the final columns, I -- I recall
 6 they could be different. But yes to an
 7 extent with the 96 value from the TD50, rat
 8 liver tumor harmonic mean, they did a linear
 9 back-extrapolation, as stated here by Roland
 10 Frotschl and explained by me in this
 11 presentation, yes.
 12 Q. And do you see the
 13 2,453-microgram number on that slide?
 14 A. Yes, I see that calculation for
 15 if the individual was exposed for the
 16 duration of 70 years to the substance, and
 17 that would be the total. And that's provided
 18 here, yes.
 19 Q. So that would be the total
 20 cumulative lifetime exposure if a patient
 21 took valsartan every day for 70 years and the
 22 tablet had 96 nanograms a day, which is the
 23 acceptable intake limit of NDMA, correct?
 24 A. According to this slide that I

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1 have not changed from Roland Frotschl, that
 2 would be correct for NDMA, if take -- I don't
 3 agree with the term "cumulative." If all
 4 those tablets were together, this would be
 5 the value that would be -- of NDMA in the
 6 total amount of tablets if taken altogether.
 7 I don't agree that it would accumulate, so I
 8 don't agree with that term, "cumulative."
 9 Q. The total amount of NDMA that
 10 the patient would be exposed to if they took
 11 a tablet of valsartan every day for 70 years
 12 that had the 96 nanograms per day acceptable
 13 intake limit; is that true?
 14 A. According to this calculation
 15 presented here by Roland Frotschl, the
 16 value -- I have no reason to state that that
 17 is an incorrect calculation. So yes, that
 18 would be the value in line with your
 19 statement.
 20 Q. So the total amount of NDMA to
 21 which the patient would be exposed, correct?
 22 A. Yes, if that patient took that
 23 particular contaminated drug for 70 years at
 24 that level, yes -- yes, according to that

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1 linear back-extrapolation from the TD50 from
 2 liver tumors.
 3 And the whole premise of my
 4 work is to put this forward as an unprecise
 5 way of doing these calculations following on
 6 from this, this amount.
 7 Q. Okay. And in your 2021
 8 research article, you proposed that the
 9 appropriate permissible daily exposure for
 10 NDMA would be 6,200 nanograms, correct?
 11 A. In that cited publication of
 12 myself, based on the assumptions put forward
 13 in that table of a 50 gram -- a 50-kilogram
 14 population and with those adjustment factors
 15 of 500 for the global population, and using
 16 the lower bound of the BMD, whereas in this
 17 report, where we're applying it to actual
 18 dose, we're using the lower and upper bound,
 19 which is the more precise and better way for
 20 this risk assessment.
 21 But that's what's presented in
 22 that publication, 50-kilogram human, BMDL10,
 23 and that's the PDE, as you've cited -- as
 24 you've cited.

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1 Q. And if one uses that PDE that
 2 is suggested by you in the research article,
 3 that the lifetime cumulative -- or let me say
 4 it a different way -- the lifetime total
 5 exposure would be 1,058,410 micrograms; is
 6 that correct?
 7 A. I do not know.
 8 Q. Well, we would arrive at that
 9 number by taking the 6.2 micrograms and
 10 multiplying that by 365 and by 70 years in
 11 order to compare it to the 2,453-microgram
 12 total that appears in this slide, correct?
 13 MS. LOCKARD: Objection,
 14 convoluted.
 15 A. This is not my calculation, but
 16 I have no reason to disagree with your
 17 calculation. So I understand.
 18 BY MS. BOGDAN:
 19 Q. The PDE that you have proposed
 20 of 6.2 micrograms, what order of magnitude is
 21 that higher than the acceptable limit
 22 established by the FDA?
 23 MS. LOCKARD: Objection,
 24 confusing.

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1 A. Approximately -- asking me to
 2 do calculations without a calculator --
 3 approximately, it looks in the order of
 4 magnitude of two orders of magnitude,
 5 approximately a hundredfold, as an
 6 approximation, potentially incorrect,
 7 required to do a calculation in my head under
 8 pressure.
 9 BY MS. BOGDAN:
 10 Q. Do you have a calculator
 11 available to you?
 12 A. Not that I'm aware of.
 13 MS. GOLDENBERG: Just use the
 14 computer.
 15 THE WITNESS: Oh, okay.
 16 MS. LOCKARD: And I'm going to
 17 object to him using -- I don't know
 18 whose computer this is, but I'm going
 19 to object to you having to do
 20 mathematical calculations on this
 21 person's computer.
 22 THE WITNESS: I do my
 23 calculations in Excel.
 24 MS. BOGDAN: Let me ask this

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1 another way which won't require very
 2 difficult math.
 3 THE WITNESS: I'm not saying
 4 it's very difficult. I'm just
 5 suggesting I don't want it on the
 6 record to do a calculation in my head.
 7 I don't think it's very difficult, but
 8 I would require a calculator in order
 9 to do this precisely, and I like
 10 precision. Sorry.
 11 BY MS. BOGDAN:
 12 Q. The FDA's acceptable intake
 13 limit is 96 nanograms, correct?
 14 MS. LOCKARD: Asked and
 15 answered, objection.
 16 MS. BOGDAN: Well, I'm just
 17 trying to walk through the
 18 calculation.
 19 A. Okay. That is correct.
 20 BY MS. BOGDAN:
 21 Q. And your proposed permissible
 22 daily exposure is 6.2 micrograms, correct?
 23 A. The proposed PDE from the lower
 24 bound for a 50-gram -- 50-kilogram population

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1 for a global population using the lower
 2 bound, not considering the upper bound as I
 3 have in my report, which is what I actually
 4 carried the risk assessment out on, but I can
 5 acknowledge your calculation, yes.
 6 Q. Well, 6.2 micrograms is what
 7 you put in your peer-reviewed published
 8 research article, correct?
 9 A. 6.2 is what I put in my
 10 peer-reviewed research article as the lower
 11 bound with these different assumptions made
 12 for a general PDE for a global population and
 13 this conceptual report, this research article
 14 that is not a risk assessment.
 15 Q. And 6.2 micrograms is 6,200
 16 nanograms, right?
 17 A. Yes.
 18 Q. So we're comparing an
 19 acceptable intake as determined by the FDA of
 20 96 nanograms to your permissible daily
 21 exposure limit of 6,200 nanograms, correct?
 22 A. That is correct. And the
 23 justification and the reason for the
 24 difference is the linear back-extrapolation

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1 does not consider dose response really at all
 2 of the cancer bioassay data, and the PDE data
 3 does, and it also considers the biology.
 4 And that accounts for the
 5 difference as outlined in my publication, in
 6 my report, to a high level of depth.
 7 Q. Is 6,200 nanograms
 8 approximately 600 times larger than
 9 96 nanograms?
 10 A. I don't want to get this wrong
 11 again, so could you say that again, please?
 12 Q. Is 6,200 nanograms
 13 approximately 600 times larger than
 14 96 nanograms?
 15 A. Is it more like 60? 60 times a
 16 hundred is 6,000.
 17 Again, asking me to do
 18 calculations without this calculator is the
 19 same issue of estimation, and I don't feel
 20 comfortable with estimations of calculations
 21 without going to this calculator.
 22 Q. Okay. If we could -- just to
 23 follow up on your last answer, so you -- is
 24 6,000 nanograms approximately 60 times larger

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1 than 100 nanograms?
 2 A. That feels more in line with
 3 the correct answer.
 4 Q. Okay. Now, on this slide
 5 that's in front of you, there is a
 6 theoretical excess lifetime cancer risk
 7 calculation that's done.
 8 Do you see that?
 9 A. I see that on this slide from
 10 Roland Frotschl. I see that, yes.
 11 Q. And is that theoretical excess
 12 lifetime cancer risk calculated assuming a
 13 320-milligram-per-day valsartan contaminated
 14 with 24.1 micrograms of NDMA for six years?
 15 A. Yes. From my understanding of
 16 this slide, that is what it states.
 17 Q. And what is the theoretical
 18 excess lifetime cancer risk associated with
 19 taking the 320-milligram-per-day valsartan
 20 contaminated with 24.1 micrograms of NDMA for
 21 six years?
 22 A. The values stated in this
 23 table, in accordance with your statement, are
 24 1 in 4,650 theoretical excess lifetime cancer

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1 risk from a 320-milligram-per-day valsartan
 2 contaminated with 24.1 microgram for six
 3 years using this linear back-extrapolation,
 4 acceptable intake, which is different to the
 5 PDE approach, which my whole report is based
 6 on.
 7 Q. And that, as shown in the
 8 slide, would be 21.5 excess cancer cases in
 9 100,000 people, correct?
 10 A. That would be the statement
 11 used, but the calculation actually just
 12 relates to animals because there's no
 13 extrapolation factor to humans. The
 14 background actual risk of cancer is 1 in 2 or
 15 1 in, say, 200 for liver.
 16 But according to this very
 17 conservative and unprecise way of calculating
 18 this, those values are 21.5 out of 100,000
 19 theoretical excess lifetime cancer risk from
 20 this linear back-extrapolation.
 21 Q. Do you know how many patients
 22 were on valsartan in the United States during
 23 the time of the contamination?
 24 A. I do not know the exact number,

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1 but I can appreciate it would be a high
 2 number as it was a very, very well prescribed
 3 drug, including some of my colleagues being
 4 on it, and my mom being on it.
 5 So extrapolating from my
 6 personal knowledge, I would see a lot of
 7 people would have been on this drug, but I
 8 don't know those numbers.
 9 MS. BOGDAN: If we could pull
 10 up the next slide, please, which is
 11 Calculation of Excess Risk for Less
 12 Than Lifetime Exposure.
 13 (Interruption by the
 14 stenographer.)
 15 (Whereupon, Deposition Exhibit
 16 Johnson-31, Demonstrative, Calculation
 17 of excess risk for less than lifetime
 18 exposure, NDMA average in API, was
 19 marked for identification.)
 20 THE WITNESS: I have that.
 21 BY MS. BOGDAN:
 22 Q. Are you able to see it?
 23 A. I'm able to see it.
 24 Q. I'm sorry, did you say you're

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1 unable to see it or you can see it?
 2 A. I can see it.
 3 Q. Do you recognize this slide?
 4 A. I recognize this slide, again,
 5 from the slide set from Roland Frotschl that
 6 he presented in a GUM meeting, a Germany
 7 mutagenicity meeting, that I have taken in
 8 order to explain or partially explain to the
 9 best of my ability this -- this approach of
 10 linear back-extrapolation carried out by the
 11 regulatory bodies, in this instance, EMA, in
 12 these issues. Yes, I do recognize it.
 13 Q. Is this slide similar to the
 14 last slide but it explains how the FDA and
 15 EMA calculated the acceptable intake for NDEA
 16 and the last slide was for NDMA?
 17 A. It does explain how the
 18 regulatory bodies, including FDA and EMA,
 19 calculated up to 26.5 in that third column
 20 for acceptable intake. And beyond that, I
 21 think there would be some differences between
 22 those bodies, but I can't state exactly what
 23 those would be.
 24 Q. And the 26.5 acceptable intake

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1 limit, is that in nanograms?
 2 A. 26.5 is in nanograms per day,
 3 as the acceptable intake calculated from the
 4 linear back-extrapolation using a 50-kilogram
 5 human, 26.5 nanograms per day.
 6 Q. And the permissible daily
 7 exposure that you calculated in your 2021
 8 publication was 2.2 micrograms or 2,200
 9 nanograms, correct?
 10 A. I can see from my publication
 11 in 2021 the PDE with these different
 12 assumptions, which is expanded upon in my
 13 report, which is a better appreciation of my
 14 actual risk assessment here than this
 15 publication, which is a more basic version.
 16 But, yes, those numbers,
 17 2.2 micrograms per person per day for NDEA,
 18 using the lower bound for the BMD and so on,
 19 with the same composite uncertainty factors
 20 at a human population at 50 kilograms, yes.
 21 Q. And 2.2 micrograms is 2,200
 22 nanograms?
 23 A. Yes, it is. I'm happy to state
 24 that that is correct.

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1 Q. And that is compared to
 2 26.5 nanograms that's the acceptable intake
 3 as calculated by the FDA, correct?
 4 A. I -- can you reword that,
 5 please? I didn't fully understand the
 6 question.
 7 Q. I'm just trying to have the
 8 comparison in the same units of measure.
 9 So the FDA's acceptable intake
 10 limit is 26.5 nanograms, as shown on this
 11 slide, and the permissible daily exposure
 12 that you calculated is 2,200 nanograms,
 13 correct?
 14 A. It's correct apart from I also
 15 expanded on the PDE as shown in my report.
 16 But that's correct. 2.2 microgram person --
 17 per day could be also in the units of 2,200
 18 nanograms per day as you stated.
 19 Q. And then going over to the last
 20 column, which is the theoretical excess
 21 lifetime cancer risk, and that was calculated
 22 for a patient taking a 320-milligram-per-day
 23 valsartan contaminated with 3.7 micrograms
 24 per tablet for four years, correct?

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1 A. According to this slide, that's
 2 correct. I'm unsure exactly how this
 3 calculation was carried out because at the
 4 top it says the API, and I didn't produce
 5 this slide and calculation myself, hence my
 6 inability to expand on that.
 7 But that's the statement here
 8 that Roland put forward at that meeting, and
 9 I don't -- I used this slide, some of this
 10 extent for my presentations. So if taking
 11 320 milligrams per day valsartan contaminated
 12 with 3.7 micrograms for four years, then his
 13 calculation were these metrics below.
 14 Q. Which would be 8 excess cases
 15 of cancer per 100,000 people, correct?
 16 A. According to his calculation,
 17 based on these figures of 3.7 micrograms of
 18 NDEA, the estimation in that large drug, the
 19 320-milligram-per-day valsartan tablet for
 20 four years, using the linear
 21 back-extrapolation from the TD50 from the rat
 22 liver tumors, with the assumption of
 23 linearity, leads to those figures at the end
 24 of 8 in 100,000 or approximately 1 in 12,500,

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1 which when we consider the actual human level
 2 of cancer of, say, 1 in 2 or 1 in 200 for
 3 liver, becomes a different way to consider
 4 these metrics.
 5 Q. But these metrics with
 6 regard -- as to how the FDA does their risk
 7 assessment is the FDA is concerned with
 8 trying to prevent excess cancer risk
 9 associated with exposure to NDEA in
 10 medication; isn't that correct?
 11 A. This is the EMA version of the
 12 calculation, so those final columns may
 13 differ to the FDA calculation, and I'm -- I
 14 didn't know the extrapolation from the API in
 15 this instance, so I could not confirm whether
 16 that is correct or not.
 17 MS. BOGDAN: If we could go to
 18 the next slide, please, which is PDEs
 19 Developed for NDMA and NDEA.
 20 (Whereupon, Deposition Exhibit
 21 Johnson-32, Demonstrative, PDEs
 22 Developed for NDMA and NDEA, was
 23 marked for identification.)
 24 THE STENOGRAPHER: Exhibit 32.

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1 BY MS. BOGDAN:
 2 Q. Do you recognize this slide?
 3 A. Still loading. It is on my
 4 screen.
 5 Yes, I recognize this slide.
 6 Q. And does this slide set forth
 7 the permissible daily exposure limits that
 8 you calculated, as reflected in your 2021
 9 publication?
 10 A. This slide represents PDE
 11 metrics from the lower bound of the BM -- of
 12 the BMD10 using these adjustment factors as
 13 stated with the same calculation as in the
 14 publication, but the unexpanded version of
 15 this that we will see in my report.
 16 Yes, this corresponds to that
 17 publication. That is correct.
 18 Q. And you have in the charts the
 19 mutagenic PDE expressed in micrograms,
 20 correct?
 21 A. The mutagenic PDE is expressed
 22 in micrograms per day.
 23 Q. Okay. And so if that was
 24 converted, for example, the NDMA mutagenic

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1 PDE of 0.6 micrograms per day -- if that was
 2 converted to nanograms, would that be
 3 600 nanograms?
 4 A. That would be a correct
 5 exchange of unit --
 6 Q. And that --
 7 A. -- by day. Per day.
 8 Q. Per day.
 9 And then similarly, underneath
 10 that, the carcinogenic PDE of 6.2 nanograms a
 11 day -- or micrograms a day, if that was
 12 converted to nanograms, that would be 6,200
 13 nanograms a day, correct?
 14 A. So that would be a correct
 15 exchange of units as we've just done
 16 previously with the same number in one of the
 17 last questions.
 18 Q. And then those could be
 19 compared in the same units of measure to the
 20 AI established by the FDA of 96 nanograms per
 21 day, correct?
 22 A. They could be compared in
 23 either unit.
 24 Q. So if we were going to convert

<p style="text-align: right;">Page 408</p> <p>1 the AI TD50 for NDMA to micrograms, that 2 would be 0.096 micrograms, correct? 3 A. Correct, per day. It needs to 4 be per day. 5 Q. Yes, per day. All right. 6 And then similarly, over for 7 NDEA, the mutagenic PDE would be converted to 8 46 nanograms per day? That would be how to 9 convert that unit from micrograms to 10 nanograms? 11 A. A conversion of a thousandfold 12 would be how you convert from microgram per 13 day to nanogram per day, correct? 14 Q. And the carcinogenic PDE for 15 NDEA would be 2,200 nanograms, correct? 16 A. It would be 2,200 nanograms per 17 day. Again, we need to add in per day. 18 Q. Well, these are all per-day 19 figures on this PowerPoint slide, correct? 20 A. The adjustment factor is not in 21 that unit, but the PDEs are in microgram per 22 day, and the AIs are currently in nanogram 23 per day. 24 Q. Now, the mutagenic PDEs that</p>	<p style="text-align: right;">Page 410</p> <p>1 conclusions from this dataset. Again, common 2 name popping up, Gollapudi, et al, 1998, 3 their group carried out the most extensive 4 NDMA dose response to date. It was the best 5 regarding close to being OECD compliant, but 6 not OECD compliant. 7 So the conclusions around the 8 mutagenic PDE are not robust enough for risk 9 assessment decisions to be made on. 10 Q. But they were robust enough for 11 you to report them in your research article 12 that you published in May of 2021, correct? 13 A. They were correct with the 14 caveats put forward in the publication, just 15 with the statements around having issues in 16 the dataset as well. 17 So correct, suitable for 18 publication. I -- but not suitable for risk 19 assessment at the current time. 20 Q. And the PDEs for mutation as 21 put forth in your published article are 22 exposures per day that would result in 23 mutation caused by either NDMA or NDEA at 24 those levels, correct?</p>
<p style="text-align: right;">Page 409</p> <p>1 appear on this slide, those are values that 2 you calculated in your 2021 publication, 3 correct? 4 A. Those were calculated from the 5 best dataset that we could find for in vivo 6 gene mutation, which was not to the level of 7 the OECD guidance and not robust enough to 8 carry out a risk assessment on. 9 But for the ability of this 10 publication, we calculated this as a proof of 11 concept to state that you could calculate the 12 PDEs in this way, and this is what they look 13 like. 14 And the lower bound of that, 15 with the assumption of quite major adjustment 16 factors totaling to 5,000 for those, that the 17 lower bound of the BMDL would be 18 0.6 microgram per day for NDEA -- NDMA. 19 NDMA. 20 Q. So that would represent, in 21 your estimation based upon your calculations, 22 the level of NDMA per day that would result 23 in mutations, correct? 24 A. I would not make robust</p>	<p style="text-align: right;">Page 411</p> <p>1 A. The units used in these 2 publications is milligrams per kilogram per 3 day for NDMA. And again, that's -- the study 4 design was not robust enough for us to make 5 solid conclusions about that for risk 6 assessment purposes. 7 But using these data, we could 8 get to 0.6 micrograms per day for NDMA or 9 0.046 micrograms per day for NDEA. 10 Is that -- did I -- apologies 11 if you need to restate the question. 12 Q. What does the mutagenic PED 13 calculation represent? 14 A. The mutagenic PDE calculation 15 represents an extrapolation from the BMD 16 lower confidence interval calculated from 17 in vivo genetic mutation data and 18 extrapolated from animals to humans -- that's 19 the first adjustment factor of 5 within the 20 adjustment factors -- to account for 21 variation in the population around DNA 22 repair, assuming that someone who doesn't 23 have any DNA repair capacity -- that's the 24 second one.</p>

<p style="text-align: right;">Page 412</p> <p>1 And then I think severity of 2 effect and exposure duration would be the 3 next 10 and the next 10. And then whether we 4 defined the final value of the point of 5 departure would be the final value. 6 So the assumption is -- you've 7 made all those assumptions and you're 8 extrapolating the mutation, BMD, to estimate 9 a potential human DNA, potential one. Again, 10 this would not be precise enough from this 11 particular dataset. And those are the sorts 12 of assumptions. 13 So this was a proof of concept, 14 and that's what these values represent. 15 MS. BOGDAN: If we could please 16 pull up Exhibit 28 again. 17 A. I have Exhibit 28 in front of 18 me. 19 BY MS. BOGDAN: 20 Q. Okay. And this, again, is the 21 February 14th, 2019 publication by the EMA. 22 If we could please go to page 24. 23 A. I'm on page 24. My page 24 24 starts with Table 10.</p>	<p style="text-align: right;">Page 414</p> <p>1 under that for the lower range, and coming up 2 with an acceptable intake limit of 9 -- 3 145 nanograms per day. 4 Do you see that? 5 A. I do see that from the linear 6 back-extrapolation of the BMDL10 rat liver 7 tumors, if you draw a straight line back from 8 them, an estimated 50-kilogram human, then 9 that calculation leads to the 145 nanogram 10 per day presented there as the acceptable 11 intake. Yes, correct. 12 Q. And then the EMA does the 13 benchmark dose approach for the upper range 14 in the next row, and derives an acceptable 15 daily intake limit of 215 nanograms. 16 Do you see that? 17 A. I do see that, but it was 18 incorrect. It's the BMD lower confidence 19 interval. That's the BL -- it's BMDL, not 20 BMD upper. 21 Q. Oh. I see. 22 A. Okay. 23 Q. So in that last row, they're 24 doing another benchmark dose lower confidence</p>
<p style="text-align: right;">Page 413</p> <p>1 Q. Perfect. 2 I'd like to direct your 3 attention to Table 10. 4 A. I'm directed. 5 Q. Okay. And the EMA is doing a 6 comparison here of the TD50 and their use of 7 the benchmark dose approach to calculate 8 theoretical excess lifetime cancer risks. 9 Do you see that? 10 A. I do see that, using the linear 11 back-extrapolation from the TD50 and the 12 benchmark dose lower confidence interval to 13 calculate theoretical risk. I do see that. 14 Q. And so the first row for the 15 TD50 rat liver tumors, do you see that? 16 A. I do see that. 17 Q. They are doing the calculation 18 and coming up with the acceptable intake 19 limit, which is the intake limit that is 20 permissible of 96 nanograms. 21 Do you see that? 22 A. I do see that. 23 Q. Okay. And then the EMA is 24 using the benchmark dose approach in the row</p>	<p style="text-align: right;">Page 415</p> <p>1 interval calculation and coming up with an 2 acceptable intake of 215 nanograms per day, 3 correct? 4 A. Yes, their use of the BMDL10 in 5 this instance, where they drew a straight 6 line back from that BMDL10 and assumed a 7 population of 50 kilograms of humans, they 8 got the acceptable intake of 215 nanograms 9 per day. I see that, yes. 10 Q. So in this table, the first 11 value, 96 nanograms, is using the linear 12 extrapolation approach from the TD50, 13 correct? 14 A. Correct, yes. Using the linear 15 back-extrapolation from the TD50 to get 96 -- 16 (audio malfunction) -- 17 (Clarification requested by the 18 stenographer.) 19 A. I will restart from the -- 20 yeah. 21 So I see the 96 nanograms per 22 day that I was directed to see. I see that 23 value and that it was calculated using the 24 TD50 from rat liver tumors with the</p>

<p style="text-align: right;">Page 416</p> <p>1 assumption of a 50-kilogram human to get the 2 acceptable intake of 96 nanograms per day. I 3 do see that. 4 BY MS. BOGDAN: 5 Q. Okay. So in this chart, the 6 acceptable intakes that are being calculated 7 by the EMA are 96 using the TD50, 8 145 nanograms using benchmark dose lower 10, 9 and then 215 nanograms using the benchmark 10 dose lower 10, correct, as shown on the 11 chart? 12 A. As shown on the document, the 13 96 refers to the linear back-extrapolation 14 from the TD50; the 145 refers to a linear 15 back-extrapolation from the BMDL10, first 16 example from the rat liver; and the final 17 value of 215 represents the linear 18 back-extrapolation from the BMDL10 rat livers 19 to calculate and present these acceptable 20 intakes for the estimated population of a 21 50-kilogram human, correct. 22 Q. And your calculation for the 23 permissible daily exposure is 6,200 24 nanograms, correct?</p>	<p style="text-align: right;">Page 418</p> <p>1 THE STENOGRAPHER: Exhibit 33. 2 BY MS. BOGDAN: 3 Q. Please let me know when the 4 exhibit is available for you to view. 5 A. Which exhibit? I can see 32. 6 Q. Can you see the short 7 commentary on NDMA? 8 A. 33? Is that Exhibit 33? Yes, 9 Short Commentary on NDMA, yes. 10 Q. And you're familiar with this 11 article, correct? 12 A. I am familiar with this 13 article, correct. 14 Q. And in this article, they do a 15 risk assessment for NDMA, correct? 16 MS. LOCKARD: Objection, form, 17 misstates the record. 18 BY MS. BOGDAN: 19 Q. Well, let's please go to 20 page 327. 21 A. I'm on page 327. 22 Q. Do you see the section entitled 23 Risk Assessment for NDMA? 24 A. I see the section Risk</p>
<p style="text-align: right;">Page 417</p> <p>1 MS. LOCKARD: Objection, form, 2 vague. 3 A. The lower bound of the PDE, as 4 you've stated as being 6.2, and adjusted to 5 nanograms or conversion of units, would be, 6 as you stated, 6,200. 7 From the lower bound of the PDE 8 from my publication, where we used the PDE 9 which assumes a threshold mechanism of DNA 10 repair, and then allows these adjustment 11 factors to calculate human risk instead of 12 drawing a straight line from the BMDL10, 13 leads to these values that you've suggested, 14 and I'm explaining a bit of the difference 15 and why they're different. 16 MS. BOGDAN: If we could please 17 pull up the next exhibit, which is 18 Snodin, Short Commentary on NDMA 19 Contamination of Valsartan Products. 20 (Whereupon, Deposition Exhibit 21 Johnson-33, Short commentary on NDMA 22 (N-nitrosodimethylamine) contamination 23 of valsartan products, by Snodin 24 et al, was marked for identification.)</p>	<p style="text-align: right;">Page 419</p> <p>1 Assessment for NDMA. 2 Q. And does Snodin in this article 3 do a risk assessment for NDMA? 4 A. I do not know. 5 Q. Okay. Directing your attention 6 to the section that's highlighted there about 7 two-thirds of the way down, there's a 8 sentence that begins "Since exposure via 9 pharmaceuticals." 10 Do you see that? 11 A. I -- can you redirect it to me? 12 Sorry, I'm getting tired. Can I see it 13 again, please? 14 Q. Okay. Sure. I think it's 15 highlighted, actually, on the Zoom, if that 16 helps you find it. 17 A. Okay. 18 Q. It's right -- 19 A. Since exposure -- I've seen it: 20 Since exposure via pharmaceuticals is 21 unlikely. 22 Q. Okay. So it reads: Since 23 exposure via pharmaceuticals is likely to 24 last more than a few years, the ICH M7</p>

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1 less-than-lifetime approach can be applied to
 2 the most conservative value of.
 3 Are you familiar with the
 4 less-than-lifetime approach?
 5 A. I have some familiarity with
 6 the less-than-lifetime approach.
 7 Q. And is that a way to do a risk
 8 assessment?
 9 A. From my understanding of the
 10 less-than-lifetime approach, it's a way to do
 11 a risk assessment and adjust an acceptable
 12 intake to less than lifetime.
 13 Q. Okay. And in this publication,
 14 that is what Snodin wrote about here in this
 15 sentence that begins "Since exposure via
 16 pharmaceuticals is unlikely to last more than
 17 a few years"?
 18 A. According to my understanding
 19 of this document and reading this specific
 20 statement, that is what it shows, that this
 21 is an explanation of the less-than-lifetime
 22 approach here, yes.
 23 Q. And then continuing on reading
 24 that sentence, please, can you tell me what

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1 values he arrived at in determining the daily
 2 exposure limit?
 3 A. Reading it out would be the
 4 result is 0.64 micrograms per day if exposure
 5 is under 10 years, and 1.2 microgram per day
 6 if exposure is under 1 year. Assume -- and
 7 that's under the assumption of the
 8 assumptions below. And this is also assuming
 9 a linear back-extrapolation, again.
 10 Q. So the daily exposure limits
 11 being calculated by Snodin would be
 12 0.64 micrograms per day if exposure is less
 13 than 10 years and 1.28 micrograms per day if
 14 the exposure is less than 1 year, correct?
 15 A. Yes, that is what's stated here
 16 due to a correction of the acceptable intake
 17 that was calculated using a linear
 18 back-extrapolation. When that's corrected
 19 here for less than lifetime, they state here
 20 those metrics which you've read out, and yes,
 21 that's what it states here.
 22 Q. And those values are, again,
 23 different than the permissible daily exposure
 24 values calculated by you, correct?

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1 A. That is correct. As one would
 2 assume from extrapolating back, a straight
 3 line from the TD50 and ignoring the
 4 dose-response relationship, you would assume
 5 that that would lead to a different value
 6 than if you accepted a nonlinear dose
 7 response with a DNA repair mechanism and
 8 carried that dose-response modeling to
 9 actually define the point of departure and
 10 extrapolate from that.
 11 And that would explain why you
 12 would see such a difference and the
 13 overconservative nature of a linear
 14 back-extrapolation approach compared to one
 15 based on nonlinearity.
 16 So that's the explanation as
 17 well as a bit more information there.
 18 Q. You stated the overconservative
 19 nature in your last response, correct?
 20 A. I stated overconservative
 21 nature in my last response.
 22 Q. When determining limits of
 23 exposure to a genotoxic mutagen, isn't it
 24 recommended to be conservative in order to

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1 minimize risk associated with exposure?
 2 MS. LOCKARD: Objection, vague,
 3 speculation.
 4 A. When assessing risk for an
 5 exposed population, it would be good to be
 6 conservative, and it would also be good to be
 7 precise. And I put forward a precise and
 8 conservative calculation in the PDE.
 9 BY MS. BOGDAN:
 10 Q. Can you point to a human study
 11 where the daily exposure limits that you have
 12 set forth have been administered to humans
 13 over an extended period of time and the
 14 results of that study have shown that those
 15 exposure limits are safe?
 16 A. There would be multiple
 17 examples that I would not be associated with,
 18 with complete drugs on the market that that
 19 statement would agree to, and another example
 20 would be -- that I was associated with, would
 21 be when we showed exactly that, that an
 22 exposed population of 25,000 people to
 23 Viracept that had a low level of EMS in a
 24 certain batch of that Viracept, we showed

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1 that that population did not have increased
 2 risk of cancer.
 3 We published on that. We put
 4 an impact story around that, submitted it to
 5 our research excellence framework. So that
 6 would be a good example to do it. So yes.
 7 There will be other examples, but that's a
 8 good one.
 9 Q. But the EMS contamination was
 10 not NDMA, correct?
 11 A. The EMS contamination was not
 12 NDMA, correct.
 13 Q. And the EMS contamination was
 14 not NDEA, correct?
 15 A. The EMS contamination was not
 16 NDEA, correct.
 17 THE WITNESS: I'm going to need
 18 some food soon. I'm getting tired.
 19 Can we talk?
 20 MS. LOCKARD: We're going to
 21 need to take a break, I think.
 22 MS. BOGDAN: Okay. We can go
 23 off the record.
 24 THE VIDEOGRAPHER: Going off

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1 the record. The time is 11:50 a.m.
 2 (Recess taken, 11:50 a.m. to
 3 12:13 p.m. BST)
 4 THE VIDEOGRAPHER: We're back
 5 on the record. The time is 12:13 p.m.
 6 BY MS. BOGDAN:
 7 Q. Dr. Johnson, are you aware that
 8 there are dietary studies that showed a
 9 statistically significant increased risk of
 10 cancer with increased dietary exposure to
 11 NDMA?
 12 A. I am aware of some food-based
 13 studies where that conclusion was made, but
 14 there was obviously a mixture within those
 15 foods of other carcinogens, but I'm aware of
 16 those studies, yes.
 17 Q. Did you determine the total
 18 exposure for those people in the studies that
 19 had a statistically increased risk of cancer?
 20 A. Can you repeat the question,
 21 please?
 22 Q. Sure.
 23 Did you calculate the total
 24 exposure to NDMA that the people in the

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1 studies who had a statistically increased
 2 risk of cancer?
 3 MS. LOCKARD: Objection, form.
 4 MS. BOGDAN: Let me ask it
 5 another way.
 6 BY MS. BOGDAN:
 7 Q. In the studies there were
 8 groups of people that had a statistically
 9 increased risk of cancer associated with
 10 certain levels of dietary exposure to NDMA.
 11 Did you calculate what those
 12 levels or exposure were for those people that
 13 had a statistically increased risk of cancer?
 14 MS. LOCKARD: Objection, vague.
 15 What studies are we talking about now?
 16 MS. BOGDAN: The dietary
 17 studies.
 18 MS. LOCKARD: Which dietary
 19 studies?
 20 THE WITNESS: I would need to
 21 see those.
 22 BY MS. BOGDAN:
 23 Q. No, I'm asking if you, at any
 24 time, calculated the total amount of NDMA

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1 that people were exposed to in the dietary
 2 studies that resulted in a statistically
 3 significant increased risk of cancer? Did
 4 you do any such calculation?
 5 MS. LOCKARD: Objection, form,
 6 vague.
 7 A. I looked at the studies in
 8 which NDMA was referenced in some food
 9 studies, and that had no link to the
 10 calculations I performed, which are PDEs, as
 11 stated on page 60 of my report.
 12 BY MS. BOGDAN:
 13 Q. So for the work you did on this
 14 case, you did not rely on any of the
 15 information in the dietary studies; is that a
 16 fair statement?
 17 A. I would state that I considered
 18 those studies and did not deem those human
 19 studies to be precise enough to be able to
 20 contribute to a human exposure limit
 21 calculation.
 22 In this instance, you would use
 23 an animal-based study, which is what I've
 24 done, as presented in my report.

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1 Q. So you chose to use an
 2 animal-based study for your calculations as
 3 opposed to the human dietary studies,
 4 correct?
 5 A. I chose to do that in line with
 6 best practice and all the other regulations.
 7 All the acceptable intakes were in line with
 8 that as well, from the relevant animal
 9 studies and not from the human studies as
 10 well. So yes, that is correct.
 11 Q. Do you agree that in the
 12 dietary studies they were seeing increased
 13 risks with NDMA levels at hundreds of
 14 nanograms per day?
 15 MS. LOCKARD: Objection --
 16 A. I would have to --
 17 MS. LOCKARD: -- form, vague.
 18 A. I would have to see the
 19 specific document to comment on specific
 20 numbers.
 21 BY MS. BOGDAN:
 22 Q. When you reviewed the dietary
 23 studies, did you make notes of the daily
 24 intakes of NDMA of the persons in the

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1 studies?
 2 A. When I saw the dietary studies,
 3 I think as referenced in one of the expert
 4 reports -- I cannot recollect which one --
 5 that targeted me towards those data.
 6 I looked at those data and saw
 7 that it was not a precise measure of just
 8 NDMA, and there would always be confounding
 9 factors within such a dietary study with over
 10 99% of known carcinogens are in food, and
 11 none of that would be accounted for by just
 12 basing the decision on one of such substance.
 13 So for that reason, it did not
 14 contribute to my report and did not -- will
 15 not change my opinion as stated in my report.
 16 Q. So the dietary studies that you
 17 did review were not used to formulate your
 18 opinion in this case, correct?
 19 A. The dietary studies were
 20 considered, as was a lot of information.
 21 They were rejected as useful sources of
 22 information for which to define and calculate
 23 a precise level of human risk that we could
 24 use as a permitted daily exposure or any

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1 other risk assessment approach.
 2 So regarding the calculations
 3 and opinions based on calculations, they
 4 formed no link to those calculations
 5 regarding metrics.
 6 Q. So you did not use the dietary
 7 studies as the basis for your opinions in
 8 this case?
 9 MS. LOCKARD: Objection, form,
 10 asked and answered.
 11 A. My opinions are based, as we
 12 can see in my report, on dose-response
 13 analysis of the most suitable cancer bioassay
 14 data, the most suitable cancer data in any
 15 species, including humans, for which you can
 16 calculate human risk.
 17 So for that reason I selected
 18 the most suitable data to calculate these
 19 human daily exposure limits, which did not
 20 include those -- those numbers from the food
 21 studies.
 22 MS. BOGDAN: Can we please pull
 23 up the Fitzgerald study, Development
 24 of Tolerable Daily Intake?

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1 (Whereupon, Deposition Exhibit
 2 Johnson-34, Development of a Tolerable
 3 Daily Intake for
 4 N-Nitrosodimethylamine Using a
 5 Modified Benchmark Dose Methodology,
 6 by Fitzgerald et al, was marked for
 7 identification.)
 8 THE STENOGRAPHER: Exhibit 34.
 9 MS. BOGDAN: Are you able to
 10 find it?
 11 TRIAL TECHNICIAN: Yep, coming
 12 up now.
 13 THE WITNESS: Yeah, I've got
 14 it. It is loaded on my screen.
 15 D. James Fitzgerald and Neville
 16 Robinson. I can see it.
 17 BY MS. BOGDAN:
 18 Q. Are you familiar with this
 19 study?
 20 A. I have seen this study.
 21 Q. And just directing your
 22 attention to page 1 of the study.
 23 A. I -- the pagination in the
 24 textbook, does that start -- is it 1670?

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1 Q. 70, correct.
2 A. Excellent. I see that.
3 Q. And do you see in the abstract
4 that these authors developed a tolerable
5 daily intake using the modified benchmark
6 dose methodology, and they report a TDI
7 range -- and this is at the bottom of the
8 abstract -- of 4.0 to 9.3 nanograms per
9 kilograms per day.
10 Do you see that?
11 A. I can see this approach of the
12 benchmark dose followed by arithmetic and
13 exponential weight averaging which, to my
14 understanding, is not in line with the
15 standardized way of carrying out benchmark
16 dose calculations in line with those from the
17 RIVM in a statistical program called PROAST,
18 which has been harmonized with the BMDS
19 software available from EPA as the go-to and
20 recommended way of carrying out BMD analysis.
21 I do not identify this as being
22 in line with that way of calculating the BMD,
23 and I see they used a 5% extra risk dose
24 where the recommendation within expert

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1 regulatory bodies would be a 10% extra risk
2 dose instead.
3 I see that using their
4 approach, they came up with those figures of
5 the BMD. And then I haven't looked -- I can
6 look at the adjustment factors that they
7 would have used to correct it to calculate to
8 the TDI.
9 So I see it and I've identified
10 some issues immediately. But I see it, yes.
11 Q. And those TDI ranges reported
12 in the study of 4.0 to 9.3 nanograms per
13 kilograms per day are different values than
14 what you calculated using your benchmark dose
15 approach, correct?
16 A. I can see that the TDI range of
17 4.93 [sic] nanograms per kilograms per day as
18 calculated from this problematic use of
19 benchmark dose modeling on these data
20 resulted in these metrics presented within
21 this abstract, yes.
22 MS. BOGDAN: Could I have a
23 time check, please?
24 THE STENOGRAPHER: 2:40.

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1 MS. BOGDAN: I'll pass the
2 witness at this point.
3 MS. LOCKARD: Okay. We'll take
4 a short break. I'm going to need
5 about -- I've got exhibits downstairs
6 I need to get pulled together, so I
7 would say probably about 15 minutes,
8 so...
9 THE VIDEOGRAPHER: Going off
10 the record. The time is 12:25 p.m.
11 (Recess taken, 12:25 p.m. to
12 1:02 p.m. BST)
13 THE VIDEOGRAPHER: We're back
14 on the record. The time is 1:02 p.m.
15 -----
16 EXAMINATION
17 -----
18 BY MS. LOCKARD:
19 Q. Dr. Johnson, how are you doing?
20 A. I'm doing great. Thank you.
21 Q. Okay. Can you spare a little
22 more time, a few more questions on the record
23 for you, and then we'll be done.
24 A. I definitely can.

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1 Q. And for the record, I'm
2 Victoria Lockard. I represent Teva. And I
3 am going to be asking the questions on behalf
4 of the defense.
5 A. Understood.
6 Q. So, Dr. Johnson, yesterday you
7 were asked if drug companies stood to benefit
8 from your PDE because it would allow them to
9 sell more drugs with higher levels of
10 nitrosamines.
11 Do you recall that?
12 A. I do recall that, yes.
13 Q. Was that your intent in
14 pursuing this area of interest?
15 A. It was not my intent when
16 pursuing this area of interest. My friend
17 and colleague came to me. He had actually
18 taken the drug, and it had been recalled. I
19 talked to my mom, and she had also taken the
20 drug and it had been recalled.
21 And I realized that in addition
22 to it relating to our current situation, it
23 would also produce peace of mind to my
24 friends and family that are on it, as well as

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1 to the exposed population and other patients.
 2 So there's quite a high level
 3 of peace of mind from knowing that you're not
 4 at increased risk of cancer from taking
 5 something. So I pursued it for that reason.
 6 Q. Okay. You mentioned that your
 7 mom was on valsartan. Did I hear you
 8 correctly?
 9 A. Yes, yes, she was on valsartan.
 10 Q. Does your PDE opinion provide
 11 peace of mind to you that your mom was not
 12 exposed to an increased risk of cancer from
 13 her medication?
 14 A. It absolutely provides that,
 15 and I have said as such to my mom.
 16 Q. Let's talk a little bit about
 17 your background and qualifications. I have
 18 put a CV in front of you. I know we have one
 19 that's attached to your report, but let's
 20 make this a standalone exhibit.
 21 What number are we on?
 22 THE STENOGRAPHER: The next one
 23 in line will be 35.
 24 MS. LOCKARD: Okay. So we'll

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1 make this Exhibit 35, just for your
 2 reference, Dr. Johnson.
 3 (Whereupon, Deposition Exhibit
 4 Johnson-35, Johnson Exhibit A,
 5 Curriculum Vitae, was marked for
 6 identification.)
 7 BY MS. LOCKARD:
 8 Q. Where is Swansea University?
 9 A. Swansea University is in Wales.
 10 It's in a city called Swansea. It's on the
 11 beach. That's where it is. It's in Wales in
 12 the U.K. in a city called Swansea.
 13 Q. Did you grow up there?
 14 A. I grew up in another seaside
 15 town called Brighton, and then I moved to
 16 Swansea.
 17 Q. Have you spent any time in the
 18 United States?
 19 A. I have spent some time in the
 20 United States.
 21 Q. Okay. Have you traveled for
 22 business around the U.S.?
 23 A. I have traveled quite
 24 extensively for business in the United

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1 States, and also for pleasure in the United
 2 States on numerous occasions as well.
 3 Q. You were explaining a little
 4 bit about the professorship levels earlier.
 5 Are the professorship levels different in the
 6 U.K. than they are in the U.S.?
 7 A. In certain universities they
 8 are. They go from -- they go from tutor,
 9 which is not on the career grade, which you
 10 would call tenure; to lecturer, which is a
 11 career grade tenure; to senior lecturer; to
 12 reader; to professor. Our university a few
 13 years ago changed from that system to
 14 harmonize better with the U.S. system.
 15 We still have the tutor, which
 16 is not tenure. We have lecturer, which is
 17 tenure. And associate professor -- senior
 18 lecturer -- sorry. I haven't done it for a
 19 while. Tutor, not tenure; lecturer, tenure;
 20 senior lecturer, tenure; associate professor,
 21 tenure with me. And the final goal is
 22 professor, full professor.
 23 Q. And are you tenured?
 24 A. Yes, I'm on the -- I'm tenured,

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1 which my interpretation is I'm in the
 2 business plan, yes.
 3 Q. And are you on track to
 4 becoming a full professor?
 5 A. I'm on track to become a full
 6 professor, and one of the last pieces of the
 7 puzzle is to either demonstrate a series of
 8 publications in high-impact journals and/or
 9 to produce a high-impact story which is
 10 assessed by our research excellence
 11 framework, which is carried out every seven
 12 years. And if that is judged by them to be
 13 four star, which is of global impact, then I
 14 will use that to apply for professorship.
 15 Q. So although you had testified
 16 at one point that you didn't get any extra
 17 pay for doing your research on the PDE that
 18 resulted in your 2021 paper, is the research
 19 that you did in connection with your PDE
 20 work -- is it part of your research
 21 obligation as a -- as a professor at the
 22 university?
 23 A. It's entirely part of my
 24 obligation as a researcher, as a professor,

<p style="text-align: right;">Page 440</p> <p>1 associate professor, in my university. I 2 publish papers. They get judged again on 3 this scale of 1, 2, 3, 4 star. If I have 4 3-star or 4-star publications, they get 5 submitted to Research Excellence Framework, 6 they contribute to my PDR, my professional 7 development review, and I'm judged I'm 8 succeeding as a researcher by publishing 9 numerous papers. 10 So this -- these publications 11 that we're commenting on today have all 12 contributed to my career progression. I'll 13 continue to research on this topic and 14 publish papers all my time at Swansea 15 University because it's part of my job. 16 Q. What qualifies as high impact? 17 A. High impact for a publication 18 has a few criteria. The easiest criteria is 19 impact factor, such as nature or science, 20 something like that. In toxicology -- and 21 this is all based on number of citations. In 22 toxicology, the impact factor is lower, say, 23 three or four. I think some of them are 24 about six. So these would be judged as</p>	<p style="text-align: right;">Page 442</p> <p>1 deemed that as the highest level of impact, 2 so we had 4-star impact in that scenario. 3 MS. LOCKARD: Okay. Steve, can 4 we pull up the Swansea University 5 Genetic Toxicology page. 6 MR. HARKINS: This is going to 7 be doc number 208 on our internal 8 tracking, marked as Exhibit 36. 9 TRIAL TECHNICIAN: Thank you. 10 (Whereupon, Deposition Exhibit 11 Johnson-36, Swansea University Genetic 12 Toxicology Webpage, was marked for 13 identification.) 14 BY MS. LOCKARD: 15 Q. So I'll hand to you a document 16 that's been marked as Exhibit 36. Do you 17 recognize this document? 18 A. I recognize this. 19 Q. What is this? 20 A. This is our impact story. 21 Q. Does this relate to the 22 Viracept publication that you were 23 referencing? 24 A. It entirely relates to that.</p>
<p style="text-align: right;">Page 441</p> <p>1 medium impact. 2 But then regarding the impact 3 story, it's has your work made an impact, 4 made a change, supported something such as 5 this, such as many individuals know that 6 they're not at increased risk of cancer, 7 that's a numerical scale. So that's an 8 impact. Everything is impact. 9 So my work is very impactful in 10 straight publication ways and in the 11 application of this work in many different 12 scenarios. 13 Q. Have you ever gotten any 4-star 14 impact recognition for any of your papers? 15 A. I think our 2007 Doak paper 16 was. Potentially another publication was. 17 More relevant to today would be we had -- I 18 think it was 2014, the last Research 19 Excellence Framework, we submitted an impact 20 story based on our contribution to the EMS 21 Viracept case. We submitted that to the 22 Research Excellence Framework, which judges 23 research excellence in a seven-year period 24 for all universities in the U.K. And they</p>	<p style="text-align: right;">Page 443</p> <p>1 And Swansea, including myself's, contribution 2 to that impact story and the evidence of the 3 impact and our link to this -- this major 4 incidence, and we detailed the impact 5 throughout in lines with what I was talking 6 about. 7 MS. BOGDAN: Could we please -- 8 excuse me -- pull up the exhibits on 9 the screen, because I can't see what 10 the witness is looking at. 11 TRIAL TECHNICIAN: Steve, 12 should I pull that up? 13 MS. LOCKARD: Do you have 14 access for the box? 15 THE WITNESS: Could we put it 16 maybe in the link? 17 TRIAL TECHNICIAN: It's in the 18 link. Would you like me to put it on 19 screen as well, Steven? 20 MR. HARKINS: Yes, if you could 21 put that on screen, that would be 22 good. Thank you. 23 TRIAL TECHNICIAN: No problem. 24 BY MS. LOCKARD:</p>

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1 Q. So why was this deemed to be a
2 high-impact piece of work, to your
3 understanding?

4 A. To my understanding, because we
5 were able to support and show that low levels
6 of this genotoxicant, this genotoxin, ethyl
7 methanesulfonate, did not increase the risk
8 to this population of 25,000 patients. That
9 was deemed of major global impact.

10 Q. And was this paper and your
11 conclusions -- were these considered by
12 certain regulatory authorities in considering
13 whether to change their regulations or their
14 guidelines?

15 A. This was submitted actually in
16 line with the guidelines at the current time
17 as presented in ICH, where they highlight
18 that if you can prove genotoxic threshold
19 mechanism with DNA repair in line with how
20 we're doing it today, if you can prove that,
21 then you can use the PDE within the ICH M7
22 guidance.

23 That whole piece, that whole
24 concept, all that data was put forward to the

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1 European Medicines Agency and accepted.

2 Q. And the EMA accepted that work,
3 which was also based on the PDE; is that
4 right?

5 A. That is correct.

6 Q. So this says on paragraph 2:
7 Previously, before 2008, genotoxicity was
8 assumed to be linear with respect to drug
9 dose and genotoxic drugs were discarded.
10 This was based on the precautionary principle
11 as no one really understood low-dose effects.

12 And do you agree with those
13 statements?

14 A. We had to broaden those
15 statements to allow a wider readership to
16 understand it, but another concept within
17 this is there was already a subgroup of
18 genotoxicants for which they were already
19 accepted to have a threshold, and those would
20 be antigens. So those were already accepted.

21 And this is really talking to
22 whether the mutagenic -- the substances that
23 interact with the DNA and cause mutations,
24 whether those same principles could be

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1 applied. And we provided our information
2 based on DNA repair and dose-response
3 analysis.

4 Q. Have you received any other
5 awards with respect to your work as a genetic
6 toxicologist?

7 A. I have, yes. So for my
8 undergraduate project, when I stated
9 previously I won the Roger Gilbert Award for
10 quantitative excellence in genetics, and
11 later on I won an award from the United
12 Kingdom Environmental Mutagen Society, UKEMS.

13 I later won an award from --
14 and these are young scientist awards -- from
15 UKEMS, and then I later won the European
16 version of that, so European Environmental
17 Mutagenesis and Genomics Society, EEMGS. I
18 won their young scientist award; later became
19 president of that, the youngest-ever
20 president for that society. I'm currently
21 vice president for that society. And I may
22 have won other awards, but those are the ones
23 I recollect.

24 Q. Do you serve on any editorial

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1 panels?

2 A. I serve on EMM, the one we've
3 discussed, to some extents, Environmental and
4 Molecular Mutagenesis. I sit on their panel
5 of editors. And that's linked to the
6 American version of the EEMGS and UKEMS,
7 which I've just stated. So I sit on that.

8 And also I sit on the Japanese
9 version of that called JEMS, Japanese
10 Environmental -- Environmental Mutagen
11 Society; their journal as well, called Genes
12 and Environment. And I don't think I sit on
13 any other ones, but I have a heavy workload.
14 I may not recollect.

15 (Interruption by the
16 stenographer.)

17 BY MS. LOCKARD:

18 Q. What do you hold degrees in,
19 Dr. Johnson?

20 A. I have an undergraduate degree
21 in genetics. I have a Ph.D. with a title
22 explained in my CV in genetic toxicology and
23 quantitative analysis of data and aspects of
24 hazard and risk assessment with a Ph.D.

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1 level.
 2 I have a teaching qualification
 3 as well, a postgraduate teaching certificate.
 4 That's a qualification. I am a registered
 5 toxicologist with BTS, British Toxicological
 6 Society, and the European version of that;
 7 and I think that's called BRT and ERT. And I
 8 think that's the extent of my qualifications,
 9 but I may have missed one.
 10 Q. And as part of your -- you're
 11 currently teaching; is that correct?
 12 A. I teach all year round,
 13 correct.
 14 Q. As part of your teaching, do
 15 you teach genetic toxicology?
 16 A. I teach genetic toxicology at
 17 undergraduate level, at master's level, at
 18 Ph.D. level, also at conferences, also with
 19 regulatory bodies, also for societies
 20 globally.
 21 Q. And do you provide
 22 presentations on risk assessments?
 23 A. Yes. Many of those
 24 presentations include risk assessment

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1 teachings, yes.
 2 Q. Have you -- and have you -- to
 3 your students, have you included -- well,
 4 strike that.
 5 Do part of your teachings that
 6 are associated with your academic appointment
 7 at the university include teaching foundation
 8 for performing risk assessments?
 9 A. We discussed that in our
 10 genetic toxicology module in undergraduate
 11 teaching. And at Ph.D. level, I have taught
 12 numerous students of mine risk assessment,
 13 and they've applied that. Many of them have
 14 got quite good jobs now in industry where
 15 they're able to apply this understanding as
 16 well. So yeah, I teach -- I teach this at
 17 many different levels.
 18 Q. So this was not the first risk
 19 assessment you had done; is that fair?
 20 A. Certainly not.
 21 Q. You were shown yesterday a
 22 document which I believe was Exhibit 3, so if
 23 we could pull that up again. And it was the
 24 2021 [sic] HESI Annual Report.

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1 TRIAL TECHNICIAN: I'm sorry,
 2 which doc number is that?
 3 MS. LOCKARD: I believe it was
 4 3.
 5 THE WITNESS: Looks correct.
 6 MS. LOCKARD: Now I'm having a
 7 problem with exhibits.
 8 THE WITNESS: They've got it up
 9 in Zoom.
 10 MS. LOCKARD: Let's see. Okay.
 11 Yep.
 12 BY MS. LOCKARD:
 13 Q. Do you remember being asked
 14 about this report and all of the
 15 pharmaceutical industry individuals who were
 16 a member or HESI yesterday?
 17 A. I do remember that with focus
 18 on the pharmaceutical individuals in this
 19 document, yes, I do.
 20 Q. What does HESI stand for?
 21 A. Health and Environmental
 22 Science Institute is what I think it stands
 23 for --
 24 Q. And --

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1 A. -- yes.
 2 Q. -- if you turn to page 2 with
 3 me of this document, can you tell us what
 4 your understanding of HESI's mission is?
 5 A. Sorry, I was on the wrong page.
 6 The vision or the mission?
 7 Q. The mission.
 8 A. The mission. HESI's mission as
 9 stated here: HESI's mission is to engage
 10 scientists from academia, government,
 11 industry, nongovernment organizations and
 12 other strategic partners to collaboratively
 13 identify and help to resolve global health
 14 and environmental changes [sic].
 15 Q. When was HESI founded?
 16 A. It was founded in 1989 as a
 17 nonprofit charitable organization.
 18 Q. You discussed yesterday this --
 19 I think you called it a tripartite approach
 20 at HESI. What did you mean by that?
 21 A. Tripartite is an essential
 22 formation of such a committee. Tripartite in
 23 this instance refers to the academic part, so
 24 it means three, tripartite. One part is

<p style="text-align: right;">Page 452</p> <p>1 academic, one part is industry, one part is 2 regulatory/government organizations. 3 Q. Does HESI hold itself out to be 4 independent? 5 A. As far as I'm aware, they do 6 hold themselves out to be independent. 7 Q. And on page 2, do you see the 8 language that says -- that says as such? 9 A. Oh. Yes. So they -- there's a 10 statement there: We are an independent 11 organization that advocates the use of 12 science in making decisions that affect human 13 and environmental health. 14 There's a strict neutrality 15 around policy issues, and our governance 16 structure requires that more public sector 17 members sit on our board of trustees than 18 private sector members. And that's a very 19 important aspect for us to consider. 20 Q. And so in your experience and 21 understanding, is HESI a pro-industry 22 organization? 23 A. No, it's a pro-science 24 organization.</p>	<p style="text-align: right;">Page 454</p> <p>1 awarded grants from FDA and a very relevant 2 one for today is FDA CDER, C-D-E-R. 3 Q. On page 3 of this document, if 4 you'll continue with me. So this appears to 5 go through the timeline of HESI starting with 6 its founding in 1989, which you already 7 testified about. 8 If you follow along with me, in 9 2014, what happened? The second 2014. 10 A. In 2014, HESI signs -- my 11 understanding of this word, MOU, I know what 12 it means, but exact phrase, I think it's 13 memorandum of understanding. 14 So HESI signs the MOU with FDA 15 CDER starting a shared commitment to 16 improving human health via enhanced 17 regulatory science partnerships. 18 MS. LOCKARD: Okay. So let's 19 have marked as Exhibit 36 -- 20 THE STENOGRAPHER: 37. 21 MS. LOCKARD: Okay. 37. What 22 was 36? 23 THE STENOGRAPHER: The last 24 exhibit.</p>
<p style="text-align: right;">Page 453</p> <p>1 Q. Is it a pro-pharma 2 organization? 3 A. It is not a pro-pharma 4 organization. 5 Q. Does HESI lobby or promote 6 legislative policy on behalf of the pharma 7 industry or chemical companies? 8 A. It definitely does not do that. 9 Q. Does HESI advocate for its 10 members, the companies or the products? 11 A. It does not. There's strict 12 rules around that. 13 Q. Does HESI pay its members or 14 scientists? 15 A. It does not. 16 Q. How is HESI funded? Is it 17 funded with grants from government agencies? 18 A. That's one aspect of its 19 funding, to include government agencies that 20 provide grants to HESI, yes. 21 Q. Are you aware that -- or do you 22 know if HESI has ever been awarded grants by 23 the U.S. Food and Drug Administration? 24 A. I am aware that they have been</p>	<p style="text-align: right;">Page 455</p> <p>1 MS. LOCKARD: Thanks. Thanks, 2 Mike. 3 TRIAL TECHNICIAN: Exhibit 35 4 was your internal 211, and then didn't 5 we go to this document, which had 6 already been marked? 7 MR. HARKINS: Sorry. 35 was 8 Dr. Johnson's CV. 36 was the Swansea 9 paper. This is our internal 10 number 205, which will be Exhibit 37. 11 (Whereupon, Deposition Exhibit 12 Johnson-37, Memorandum of 13 Understanding Between USFDA and HESI, 14 was marked for identification.) 15 MS. LOCKARD: Okay. So if we 16 can pull that up. 17 BY MS. LOCKARD: 18 Q. Have you seen this document 19 before? 20 A. I've seen it, but I haven't 21 read it in huge detail. I've seen it. 22 Q. Okay. Can you just read up at 23 the top the title of the document for us? 24 A. The title of the document is</p>

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1 Memorandum of Understanding Between the U.S.
 2 Department of Health and Human Services, the
 3 Food and Drug Administration, and ILSI, HESI,
 4 ILSI Health and Environmental Science
 5 Institute, so yeah.
 6 Q. So under the Purpose section of
 7 this document, it says: The United States
 8 Food and Drug Administration, FDA, and ILSI
 9 Health and Environmental Sciences Institute,
 10 parentheses, HESI, share interests in
 11 promoting scientific progress through the
 12 exchange of scientific capital to address and
 13 reach consensus on scientific questions
 14 impacting the development of FDA-regulated
 15 products and the evaluation of human safety.
 16 Has that been your experience
 17 at HESI?
 18 A. That has definitely been my
 19 experience at HESI. Hence, some of my
 20 publications you'll see coauthorship with --
 21 within this group with experts from FDA on
 22 that that are members directly of our
 23 subgroup at GTTC. So I definitely recognize
 24 and acknowledge this.

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1 Q. If you look about halfway down
 2 the paragraph on Purpose, the sentence that
 3 starts "The FDA"?
 4 A. "The FDA and HESI," that one?
 5 Q. Yes.
 6 A. I see that.
 7 Q. The FDA and HESI, partners,
 8 desire to collaborate on multiple activities,
 9 including: developing new methods to evaluate
 10 the toxicity of substances regulated by the
 11 FDA.
 12 Do you see that?
 13 A. I do see that.
 14 Q. And is that the same purpose
 15 that you were trying to achieve in developing
 16 your PDE calculation and submitting that for
 17 publication?
 18 MS. BOGDAN: Objection to the
 19 form.
 20 A. That's entirely related to that
 21 publication and the publications leading up
 22 to that where we outlined the topic in
 23 extensive detail about how this approach can
 24 be carried out.

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1 BY MS. LOCKARD:
 2 Q. So does FDA rely on and expect,
 3 to your knowledge of the agreement, the
 4 memorandum of understanding, expect that HESI
 5 will follow and develop the science with
 6 respect to, you know, new issues of concern,
 7 new evaluations of toxicity, and the kinds of
 8 things that we've been talking about today?
 9 Do they expect HESI will be on
 10 the forefront of those items?
 11 A. They expect --
 12 MS. BOGDAN: Objection to the
 13 form, compound, speculative.
 14 A. From my assumption, from my
 15 experience with FDA, experts within the HESI
 16 group, I do see that they acknowledge that
 17 the HESI group is at the forefront of exactly
 18 this, in developing new methods to evaluate
 19 the toxicity of substances regulated by the
 20 FDA. Definitely at the forefront of this.
 21 BY MS. LOCKARD:
 22 Q. Do you feel that that is
 23 something that has been encouraged by the
 24 collaboration between FDA and HESI?

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1 A. I think I am confident in
 2 saying I do think I support that statement,
 3 yes.
 4 Q. Turning back to the last
 5 exhibit we were on, which was the HESI Annual
 6 Report.
 7 A. Yeah, I have it.
 8 Q. Okay.
 9 A. So back to the HESI report?
 10 Q. Yes.
 11 Have you ever seen HESI and FDA
 12 host --cohost workshops?
 13 A. I have seen workshops where
 14 HESI and FDA are participants.
 15 Q. You were asked questions about
 16 the membership of HESI. If you can turn with
 17 me to page 4 of this document, and do you see
 18 a graphic there?
 19 A. Yeah, I do see a graphic there.
 20 Q. And there's a green graphic
 21 near the -- I guess tell me what does this
 22 green graphic mean there in terms of the
 23 makeup of HESI?
 24 A. From my understanding of this

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1 green aspect of this little chart, is it
2 shows that we have 291 partners at this time
3 of publication. A large proportion of that,
4 124, from academia, which are universities;
5 61 from government/regulatory agencies -- and
6 to my understanding, that's probably nearly
7 all of them. That's a lot of
8 government/regulatory agencies -- 80 from
9 industry; 26 from NGOs, which I think is
10 nongovernment organizations. There's also
11 research institutes and others.

12 So that's my understanding of
13 the breakdown of these partners.

14 Q. So if I understand your
15 testimony about this document, there are far
16 more academic partners than there are
17 industry partners according to this graphic
18 in the annual report, correct?

19 A. Definitely correct, according
20 to these numbers in this annual report.

21 Q. Do you know whether out of the
22 government/regulatory agencies, is EMA one of
23 the agencies that is a government partner
24 with HESI?

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1 A. I am not a hundred percent
2 sure, but I know that EMA experts being
3 within our committee for numerous years
4 within the GTTC, but I'm unsure if they have
5 it under their EMA titles and/or their local
6 regulatory titles. Apologies for the
7 unsurety -- uncertainty.

8 MS. LOCKARD: Okay. Let's pull
9 up the next exhibit, which will be 38.

10 MR. HARKINS: Chris, this will
11 be 207 from our internal tracking,
12 introduced as Exhibit 38, and if you
13 could please screen-share. Thank you.
14 (Whereupon, Deposition Exhibit
15 Johnson-38, HESI Government Agencies
16 Webpage, was marked for
17 identification.)

18 MS. LOCKARD: That's fairly
19 small. We might be able to pull it up
20 on the document link.

21 THE WITNESS: Number 37, is
22 that correct?

23 THE STENOGRAPHER: 38 is the
24 new one.

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1 MS. LOCKARD: 38.
2 THE WITNESS: Is it up there
3 yet? Excellent, I can see it. It is
4 on my screen, and I need to enlarge
5 it.
6 I can now see it.
7 BY MS. LOCKARD:
8 Q. So this is a -- you can see
9 from the top, the website for
10 hesiglobal.org/partner, and a listing of our
11 partners.
12 Are you familiar with the HESI
13 website?
14 A. I'm very familiar with the HESI
15 website.
16 Q. And so does this appear to be a
17 listing of the HESI government agency
18 partners?
19 A. This appears to be a list. I'm
20 unsure if it's the full list, but I identify
21 this as a list of government agencies within
22 the HESI group.
23 Q. Okay. And if you look on the
24 first column, four down, the European

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1 Medicines Agency is listed.
2 Do you see that?
3 A. I see that. I see that and I
4 can now confirm from seeing this the European
5 Medicines Agency is a partner of HESI.
6 Q. Let's look down at the bottom
7 of the first page, right column, bottom row,
8 the NIH, National Cancer Institute, are you
9 familiar with that organization?
10 A. To an extent. I realize
11 they're a very well-regarded institute. I
12 do -- I am aware of them.
13 Q. Okay. And does this indicate
14 they are a member, a governmental member of
15 HESI?
16 A. This does indicate that, and
17 I -- yes, it does.
18 Q. Do you see Health Canada on the
19 list?
20 A. I do see Health Canada on the
21 list, and there's many participants in our
22 GTTC from Health Canada.
23 Q. Do you see -- on the second
24 page, do you see where the USFDA is listed as

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1 being a member of HESI?

2 A. Yes, I do see that, and also

3 different subsets of FDA as well.

4 Q. And at the top of page 2, do

5 you see where the National Institutes of

6 Health is listed as being a member of HESI?

7 A. I -- I do, and I think we have

8 some NIH experts within our own committee as

9 well, GTTC.

10 MS. LOCKARD: Next, Exhibit 39.

11 MR. HARKINS: This will not be

12 a separate exhibit. It's a

13 continuation of the same, if you

14 continue to scroll down.

15 MS. LOCKARD: Oh, okay. I see.

16 So if you can pull up 38 again

17 and scroll down.

18 THE WITNESS: I've done that.

19 I'm on page 3 of that.

20 BY MS. LOCKARD:

21 Q. Okay. Up at the top of this,

22 similarly, it's a page from HESI's website.

23 Do you recognize it as such?

24 A. I do recognize it as such.

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1 Q. And at the top of the listings,

2 do you see where it says Academic

3 Institutions?

4 A. I do see where it says Academic

5 Institutions.

6 Q. So in terms of the tripartite

7 organization, you talked about some industry,

8 pharma members yesterday, and we've now

9 covered governmental members, and so this

10 would be the third leg or so of that

11 tripartite, the academic institutions?

12 A. I fully agree with that, and

13 yes, this is the list of the academic

14 institutions.

15 Q. Is Swansea on this list?

16 A. Yes, it is.

17 Q. And do you see a number of

18 well-recognized U.S. academic institutions on

19 this list?

20 MS. BOGDAN: Objection to the

21 form.

22 A. I do see a list of high-end,

23 very excellent universities from America on

24 this list.

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1 BY MS. LOCKARD:

2 Q. Do you see Columbia on this

3 list?

4 A. Columbia? I see Columbia

5 University on this list.

6 Q. Do you see Cornell on this

7 list?

8 A. I see Cornell University on

9 this list.

10 Q. Do you see Harvard on this

11 list?

12 A. I see Harvard University on

13 this list.

14 Q. Do you see Johns Hopkins on

15 this list?

16 A. I see Johns Hopkins University

17 on this list.

18 Q. Do you see MIT on this list?

19 A. I see MIT on this list.

20 Q. Do you see Stanford University

21 on this list?

22 A. I do see Stanford University on

23 this list.

24 Q. Okay. If we can go back, once

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1 again, to Exhibit 13, which is the

2 Annual Report.

3 THE STENOGRAPHER: 3.

4 MS. LOCKARD: Excuse me, 3,

5 Exhibit 3.

6 BY MS. LOCKARD:

7 Q. And again, yesterday, in the

8 questioning by plaintiffs' counsel, you were

9 asked questions about all of the industry

10 members who serve on the toxicology

11 committee.

12 A. Yes, that's true.

13 Q. Do you recall that?

14 A. Yeah.

15 Q. And that's the committee that

16 you're most involved in; is that correct?

17 A. That is correct. That is my

18 committee I am very involved in.

19 Q. Okay. So turning to page 35,

20 if we can pull that up on the screen.

21 So in addition to all the

22 industry corporations that were named

23 yesterday, are there also a number of

24 government/regulatory agencies and academic

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1 research institutes listed as participants in
 2 the toxicological division of HESI?
 3 A. Yes, there is a list here of
 4 the government/regulatory agencies linked to
 5 HESI, enrolled and participate in the HESI
 6 Genetic Toxicology Technical Committee.
 7 Q. Including those participating
 8 on the genetic toxicology committee, did
 9 that -- does that include the USFDA as well,
 10 according to this annual report?
 11 A. Yes, it does include the USFDA
 12 in this report.
 13 Q. And is your university,
 14 Swansea, listed on here along with a number
 15 of other academic research institutes?
 16 A. Yes, Swansea University is
 17 listed here along with other academic and
 18 research institutes.
 19 Q. And if you look down at the
 20 industry list that you went over the other
 21 day or yesterday -- I'll give you a second to
 22 glance at that -- do you see anywhere on this
 23 industry list the name Teva Pharmaceuticals?
 24 A. I'm looking at the bottom, and

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1 the only ones in T are -- there's two
 2 beginning with T, and neither of those are
 3 Teva. So, no, I do not see Teva
 4 Pharmaceuticals there.
 5 Q. Do you see Torrent on this
 6 list?
 7 A. I do not see Torrent on this
 8 list.
 9 Q. Do you see ZHP or Princeton on
 10 this list?
 11 A. I do not see ZHP on this list.
 12 Q. Do you see Aurobindo on this
 13 list?
 14 A. I do not see Princeton on this
 15 list.
 16 I do not see Aurobindo on this
 17 list.
 18 Q. Do you see Mylan on this list?
 19 A. I do not see Mylan on this
 20 list.
 21 Q. To your knowledge, are any of
 22 the defendant manufacturers involved in this
 23 case partners at HESI?
 24 A. To my understanding, I do not

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1 think that they are partners of HESI.
 2 Q. Let me ask you if you have an
 3 understanding why -- why would -- I guess
 4 were you surprised by that, that the
 5 manufacturers are not involved in HESI?
 6 MS. BOGDAN: Objection to the
 7 form.
 8 A. I am not surprised by that.
 9 The defendant companies, from my
 10 understanding, are focused on generic
 11 pharmaceuticals. And when we carry out
 12 genetic toxicology, that's through -- only
 13 through the whole drug development and
 14 production pipeline to which we apply genetic
 15 toxicology and cancer risk assessment
 16 applications.
 17 Any issues within that, we --
 18 we research to a great extent. So if you're
 19 involved in the drug discovery and
 20 development pipeline, you would have a great
 21 interest in the new and best approaches in
 22 genetic toxicology.
 23 My understanding is with
 24 generic pharmaceutical companies, it's a

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1 different process and it's more production of
 2 patent -- or out-of-patent, already accepted
 3 pharmaceuticals to which these concepts apply
 4 to a much -- much lesser extent.
 5 So I would not predict their
 6 level of interest in these advanced
 7 applications would lead them to want to be a
 8 part of it. So it's not surprising to me at
 9 all.
 10 BY MS. LOCKARD:
 11 Q. Have you ever worked at
 12 Exponent?
 13 A. I have not worked at Exponent.
 14 Q. Do you recall being shown a
 15 document yesterday that essentially
 16 criticized Exponent and it was published by
 17 an entity listed as FairWarning?
 18 A. I do remember that.
 19 Q. Have you ever heard of
 20 FairWarning?
 21 A. I have never heard of
 22 FairWarning.
 23 Q. Not even the 1991 Van Halen
 24 album?

<p style="text-align: right;">Page 472</p> <p>1 Have you ever heard criticisms 2 like that about Exponent before? 3 A. I have not heard criticisms 4 about Exponent along those lines. 5 Q. And the things that were 6 described in that article, what was the time 7 period of that? Do you recall? 8 A. I recall the major criticism 9 seeming to be in the 1990s if that's correct. 10 Q. Was that before you had written 11 papers with any Exponent member? 12 A. That is definitely before I had 13 written papers with Exponent and before I had 14 qualified in this area. 15 Q. And you've worked with Exponent 16 scientists in writing or coauthoring papers, 17 such as Bhaskar Gollapudi, correct? 18 A. That is correct. 19 Q. And what was your impression or 20 experience with the Exponent scientists? 21 A. My impression of Bhaskar 22 Gollapudi is he's an excellent genetic 23 toxicology expert. He's brilliant at this 24 area. He understands all the concepts to a</p>	<p style="text-align: right;">Page 474</p> <p>1 of that relate to you or your PDE paper? 2 A. It does not at all from my 3 perspective. 4 Q. You were also asked a number of 5 questions about disclosure of conflict of 6 interests. Do you recall that as well? 7 A. I recall that as well. 8 Q. And I believe you were asked 9 specifically about the Heflich article at 10 Exhibit 10; the first author, White, 11 Exhibit 12; Gollapudi, Exhibit 13; Wheeldon, 12 Exhibit 14; and then the Elder commentary, 13 Exhibit 18. 14 And do you recall the questions 15 about disclosure of conflict of interest for 16 each of those? 17 A. I recall extensive discussions 18 and series of questions about those topics, 19 about those publications with conflict of 20 interest being the focus. 21 Q. Okay. Why did you not disclose 22 a conflict of interest in any of those 23 papers? 24 A. Because they were not related</p>
<p style="text-align: right;">Page 473</p> <p>1 high level and has applied knowledge of how 2 to apply that in hazard and risk assessment. 3 He's an excellent scientist and seems to be 4 good at applying these concepts in this 5 hazard and risk assessment framework. 6 And the other authors that we 7 saw on the ethylene oxide publication were 8 very good at -- we were looking at the whole 9 wealth of information on that particular 10 substance and working together. They were 11 amazingly extensive in leaving nothing 12 unturned and analyzing the huge amounts of 13 data together, and they were great as well. 14 So, you know, I have no issues 15 with them. 16 Q. Well, to the extent that any of 17 those allegations in that article were true, 18 does any of that relate to you or your 2021 19 paper at all? 20 A. Can you repeat the question, 21 please. 22 Q. To the extent that any of the 23 allegations in that FairWarning document that 24 you were shown yesterday are true, does any</p>	<p style="text-align: right;">Page 475</p> <p>1 to this publication. 2 Q. They're not related to your 3 work in this case? 4 A. They're not related to the work 5 in this case. 6 Q. Was there a conflict of 7 interest that you failed to disclose? 8 A. There was not a conflict of 9 interest that I failed to disclose. 10 Q. Did you disclose in your PDE 11 2021 paper that you were in the -- that you 12 were a consultant on behalf of pharmaceutical 13 companies? 14 A. A statement included 15 information that I regard as being specific 16 to address that case, yes. 17 MS. BOGDAN: Please note my 18 objection to form to the last 19 question. There was a little delay. 20 BY MS. LOCKARD: 21 Q. Did you disclose your 22 relationship with the companies in this case 23 for whom you have performed a risk assessment 24 in your 2021 PDE paper?</p>

<p style="text-align: right;">Page 476</p> <p>1 A. I did produce a conflict of 2 interest that covers that, my relationship 3 within the conflict of interest statement in 4 that publication, yes.</p> <p>5 Q. Did you ever share your draft 6 2020 PDE paper with Teva or any other 7 manufacturer before submitting it?</p> <p>8 A. I did not submit a draft 9 prepublished version to GT and the -- are we 10 defendants? Defendants. But you see from 11 the coauthorship of the publication that 12 there are some pharmaceutical industries 13 included as authors who would have seen the 14 draft because they helped to write it.</p> <p>15 Q. Did anyone at GT or Teva or on 16 behalf of any other manufacturer provide 17 input into what should go into your PDE 2021 18 paper?</p> <p>19 A. They did not provide that 20 information at all.</p> <p>21 Q. You were asked questions about 22 your PDE approach and the comparison of it to 23 the AI approach that was adopted by FDA. 24 Do you remember answering those</p>	<p style="text-align: right;">Page 478</p> <p>1 the weights that you applied and the ultimate 2 calculations that you rendered in your 2021 3 paper.</p> <p>4 And when you were asked about 5 your paper, the questions primarily 6 surrounded the PDE that you generated for -- 7 in the paper for patients who were at or 8 around 50 kilograms. Is that right?</p> <p>9 A. That is how I interpreted the 10 question, with focus on my publication, not 11 on my report.</p> <p>12 Q. So if you look at your report, 13 you have a different weight, upper weight 14 limit that you've taken into account in this 15 risk assessment; is that fair?</p> <p>16 A. That is fair.</p> <p>17 MS. BOGDAN: Objection to the 18 form.</p> <p>19 BY MS. LOCKARD:</p> <p>20 Q. Where is it demonstrated in 21 your report? What page are you on?</p> <p>22 A. Page 60 is where there's an 23 explanation around this 100-kilogram 24 calculation as well. Page 60 of my report.</p>
<p style="text-align: right;">Page 477</p> <p>1 questions?</p> <p>2 A. I remember answering those 3 questions, and the PDEs discussed were almost 4 entirely from the publication and not from my 5 report, and I tried to answer by bringing in 6 the PDEs and the confidence intervals and 7 different calculations for a 100-kilogram 8 human into my answers.</p> <p>9 Q. Well, let's -- I believe we 10 marked your report as an exhibit in this 11 case?</p> <p>12 TRIAL TECHNICIAN: Exhibit 25 13 [sic].</p> <p>14 MS. LOCKARD: 25. Let's pull 15 that up.</p> <p>16 THE STENOGRAPHER: I'm tracking 17 that as Exhibit 2, not 25.</p> <p>18 MS. LOCKARD: Oh. Who said 25?</p> <p>19 TRIAL TECHNICIAN: That's my 20 internal number, my apologies. Yes, 21 it's marked as Exhibit 2.</p> <p>22 BY MS. LOCKARD:</p> <p>23 Q. Okay. So if we look at 24 Exhibit 2, you were being questioned about</p>	<p style="text-align: right;">Page 479</p> <p>1 Q. Okay. Can you explain for the 2 record what and why you added the 3 100-kilogram factor into your report in this 4 case when it was not in your 2021 paper?</p> <p>5 A. The average population weight 6 in America and for Europe as well is not 50. 7 So if we're looking to use an applicable 8 human weight, such as inline with something 9 like the CDC, which puts forward the 10 population weights, and considering further 11 details as well that I've requested, 12 actually, from GT, the 100-kilogram would be 13 much more applicable to the population 14 exposed in this incidence, and as discussed 15 and looked into, when requested, I think -- 16 they call it a bellwether --</p> <p>17 Q. Okay.</p> <p>18 A. -- correct? When I requested 19 for details of actual weight of some people 20 exposed, and we did a calculation, looked at 21 it, 100 kilograms was much more in line with 22 this population.</p> <p>23 Q. And so you're familiar with the 24 Centers For Disease Control or the CDC here</p>

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1 in the -- or in the United States?
 2 A. Yes, I am.
 3 Q. Are you aware that CDC
 4 publishes tables listing the mean weights for
 5 females and males in the U.S.?
 6 A. I am fully aware of that and I
 7 have seen it. I used that for my
 8 interpretations.
 9 MS. LOCKARD: Let's have that
 10 marked as well as the next exhibit,
 11 38.
 12 THE STENOGRAPHER: 39.
 13 MS. LOCKARD: 39. I was led
 14 astray.
 15 MR. HARKINS: Victoria, this is
 16 the bellwether weights?
 17 MS. LOCKARD: No, this is the
 18 CDC. Do you have that to pull up?
 19 MR. HARKINS: I do not.
 20 MS. LOCKARD: Okay. Well,
 21 that's okay. I've got a copy of it.
 22 We'll come back to that. I've got a
 23 copy of it downstairs. Okay.
 24 (Whereupon, Deposition Exhibit

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1 Johnson-39, USFDA Anthropometric
 2 Reference Data for Children and
 3 Adults: United States, 2015–2018, was
 4 marked for identification.)
 5 BY MS. LOCKARD:
 6 Q. But your understanding is so
 7 there is data that is publicly available from
 8 the CDC, which you reviewed as to weight.
 9 You described that, and you were describing
 10 in addition, you reviewed some specific
 11 information about valsartan plaintiffs
 12 involving their weights; is that correct?
 13 A. Both of those statements are
 14 correct.
 15 MS. LOCKARD: Okay. So we'll
 16 make -- we'll leave the CDC as the
 17 last exhibit, even though we'll mark
 18 it, the actual document, later.
 19 And the next exhibit will be
 20 what I'm handing the witness now, and,
 21 Mr. Harkins, you can pull that up on
 22 the screen.
 23 MR. HARKINS: This will be 201
 24 from our internal tracking, and if you

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1 could please screen-share.
 2 (Whereupon, Deposition Exhibit
 3 Johnson-40, Valsartan Bellwether
 4 Plaintiffs' Weights, was marked for
 5 identification.)
 6 BY MS. LOCKARD:
 7 Q. And is this a document that you
 8 worked on with GT?
 9 A. This is a document that I
 10 requested for me to investigate and to allow
 11 me to assess my PDEs to this population, and
 12 that was linked and with GT.
 13 Q. And is -- what is your
 14 understanding of what is reflected in this
 15 chart that is supportive of your conclusions
 16 in your report?
 17 A. My assumption that the average
 18 weight of the population that we would be
 19 considering would be closer to 150, and if we
 20 look at the averages at the bottom, they are
 21 all 97 with decimal places, okay? At the
 22 bottom, the average, the median and the
 23 midpoint are all closer to 100 than they are
 24 to 50, and I thought this was an interesting

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1 and useful bit of information.
 2 Q. So you -- why did you not --
 3 why did you include the 100-kilogram input
 4 into your risk assessment here, but not into
 5 your 2021 PDE publication?
 6 A. Into the PDE publication, those
 7 calculations for regulatory limit would be
 8 based on 50 kilograms to cover the whole
 9 global population when we don't have
 10 information about individual body weights and
 11 we don't have a focused population.
 12 And there's two reasons I
 13 included it here, one, to show what the PDEs
 14 and the concentrations where there would be
 15 no levels of increased risk of cancer, and
 16 around these concentrations for 50 and 100,
 17 and also to show conceptually that this
 18 calculation can be tailored towards different
 19 populations and even individuals as well. I
 20 wanted to get this written in a clear way.
 21 Q. Are your conclusions in this
 22 report regarding the levels you've calculated
 23 for 100-kilogram patients, is that consistent
 24 with your conclusions in the publication with

<p style="text-align: right;">Page 484</p> <p>1 regard to 50-kilogram patients in terms of 2 your methodology? 3 A. In terms of my methodology, 4 calculations are very similar. Apart -- 5 there's the differences that I've put forward 6 are the 100 kilograms. Another difference in 7 the report is around the confidence 8 intervals. 9 The things with confidence 10 intervals in benchmark dose and with any 11 level of human risk, if you have a single 12 data point, there's no measure of precision, 13 there's no measure of uncertainty. 14 Recommended for myself and 15 other experts, particularly from the BMD 16 field, you should present both metrics. This 17 covers precision and uncertainty. 18 And there's been statements 19 from such experts that if you base it on a 20 single data point, such as with the TD50, 21 single data point, no measure of uncertainty 22 and so on, those results are actually 23 meaningless. And that's a direct quote from 24 Wout Slob on this particular topic.</p>	<p style="text-align: right;">Page 486</p> <p>1 approach that can be further tailored to 2 ensure that the exposed population aren't at 3 increased risk, and I'm confident in saying 4 that they are not at increased risk in the 5 exposures that I've seen. 6 Q. You mentioned an MGMT 7 deficiency. Are you comfortable in your 8 assumptions that none of the plaintiffs that 9 you've reviewed in that weight chart have an 10 MGMT deficiency? 11 A. I -- it's a prediction. MGMT 12 deficiency is very rare and very lethal, and 13 to get to any age of adulthood with MGMT 14 deficiency is very unlikely. 15 We include that in a global 16 population with the generic PDE because we 17 have to make an assumption, but in a more 18 tailored population that we can actually 19 follow and have a look, I'm comfortable that 20 you can move this -- that you could make that 21 distinguishment between 10 and 1 for that -- 22 to cover that. 23 Q. One of the -- one of the 24 criticisms I think you mentioned of the FDA's</p>
<p style="text-align: right;">Page 485</p> <p>1 So I presented those, the 2 confidence intervals, lower and upper bound 3 from the BMD, calculated the PDE, lower and 4 upper confidence intervals. So that was an 5 update and something of interest here. 6 And another step as well that 7 we could go towards with a population that we 8 know a bit more about is the composite 9 uncertainty factors. We think the cancer -- 10 one of the composite uncertainty factors is 11 10; one of those 10 counts for heterogeneity 12 of the population for DNA repair. 13 So unless we can prove the 14 individual has not got MGMT deficiency, that 15 provides me confidence that that 10 can be 16 reduced to a zero, and then that composite 17 uncertainty factor reduces from 500 to 50, 18 and that directly means that our PDE limits 19 were increased actually by an order of 20 magnitude, so multiplied by ten in this 21 instance. 22 So I hope that explains the 23 detail of this, the extra information in 24 this, and that this is a very tailored</p>	<p style="text-align: right;">Page 487</p> <p>1 approach -- approach or using the TD50 was 2 that it doesn't take into account endogenous 3 sources. Can you explain that? 4 A. With the TD50, it's a 5 calculation of high-dose -- at a high-dose, 6 high-response part of the dose-response 7 curve. 50% of the animals in that example 8 got cancer, way far beyond the background 9 level. 10 And then there's a straight 11 line that's drawn back to calculate 1-in-100 12 risk in animals -- not humans, but they say 13 it's humans -- so 1 in 100,000. So a 14 straight line back to that. 15 There's no account for 16 endogenous levels really in that straight 17 line from the middle of the high-dose level 18 back to -- back to zero. 19 With another approach with the 20 dose-response modeling such as BMD, we're 21 including the dose-response information in 22 the low-dose region around the points of 23 departure to which we're discussing 24 background levels with -- we're discussing</p>

<p style="text-align: right;">Page 488</p> <p>1 those, we're analyzing it around that</p> <p>2 low-dose region, which to my understanding</p> <p>3 has a better reflection on the background and</p> <p>4 endogenous sources of such DNA damage, and</p> <p>5 also when you apply the PDE approach on top</p> <p>6 of this, I think it just better reflects a</p> <p>7 more precise measure that would better</p> <p>8 encompass that inclusion of endogenous</p> <p>9 sources.</p> <p>10 Q. Does the AI methodology</p> <p>11 consider DNA repair?</p> <p>12 A. It completely ignores DNA</p> <p>13 repair in a very -- it really ignores the DNA</p> <p>14 repair and draws a straight line from the</p> <p>15 high-dose, high-response part of the</p> <p>16 dose-response curve, ignoring any information</p> <p>17 below that by drawing a straight line from</p> <p>18 there back to the origin, ignoring what the</p> <p>19 dose-response curve actually looks like.</p> <p>20 And that part of the</p> <p>21 dose-response curve is where we can</p> <p>22 characterize and show and have shown that DNA</p> <p>23 repair contributes to that low-dose level</p> <p>24 where not much is going on, and that's why we</p>	<p style="text-align: right;">Page 490</p> <p>1 sense of why FDA and EMA did not immediately</p> <p>2 adopt your PDE approach?</p> <p>3 MS. BOGDAN: Objection to the</p> <p>4 form, speculative.</p> <p>5 A. My opinion is they -- if they</p> <p>6 were in a reactive situation, the impurities</p> <p>7 were in the drugs, there were certain</p> <p>8 patients taking them. They found this out</p> <p>9 and had to make a decision very, very quickly</p> <p>10 in a harmonized way that everyone could agree</p> <p>11 on very, very quickly.</p> <p>12 They did that with the TD50</p> <p>13 approach. They did that with the acceptable</p> <p>14 intake based on the back of that in a</p> <p>15 reactive way that was able to make -- help</p> <p>16 them make the decision and justify taking the</p> <p>17 drugs off the market. Okay. That's</p> <p>18 understood.</p> <p>19 And then when the PDE came</p> <p>20 along, the justification for using it would</p> <p>21 be on the DNA repair discussion point, and as</p> <p>22 I've stated, there's interest from the EMA</p> <p>23 and they're putting the money forward and</p> <p>24 we're working together to get that DNA repair</p>
<p style="text-align: right;">Page 489</p> <p>1 can justify that DNA repair can support a</p> <p>2 threshold mechanism, can support a nonlinear</p> <p>3 dose response, and the linear</p> <p>4 back-extrapolation does not remotely consider</p> <p>5 that information.</p> <p>6 Q. Did the FDA ever reject your</p> <p>7 PDA model -- excuse me, PDE model?</p> <p>8 A. The decisions made by FDA were</p> <p>9 made prior to my publication, so they would</p> <p>10 not have been that time frame.</p> <p>11 Q. And the guideline that you were</p> <p>12 shown from today that was made an exhibit, do</p> <p>13 you recall that the timeline of that</p> <p>14 publication was February 2021?</p> <p>15 A. That sounds like a correct</p> <p>16 date. I can see.</p> <p>17 Q. How many months before that was</p> <p>18 your publication of your paper?</p> <p>19 A. My publication was in May 11th,</p> <p>20 2021.</p> <p>21 Q. So given your -- the</p> <p>22 relationship that you have with HESI and</p> <p>23 interactions with regulators, industry and</p> <p>24 other scientists like yourself, do you have a</p>	<p style="text-align: right;">Page 491</p> <p>1 information together in our grant. So maybe</p> <p>2 not yet.</p> <p>3 When we get our information</p> <p>4 together, there will be a position and</p> <p>5 consideration to a big extent again for PDE,</p> <p>6 as far as I'm aware.</p> <p>7 BY MS. LOCKARD:</p> <p>8 Q. You spoke a little bit early in</p> <p>9 the deposition about hazard versus risk, and</p> <p>10 I believe you commented that the IARC model</p> <p>11 had moved away from a risk-based to a</p> <p>12 hazard-based approach. Is that -- is that</p> <p>13 what you testified to?</p> <p>14 A. That is what I testified to,</p> <p>15 and I would -- I stick to that testimony as</p> <p>16 well. The IARC, from my understanding and</p> <p>17 also from my understanding of their recent</p> <p>18 change in name to recognize this, is they've</p> <p>19 changed and acknowledged that they're a</p> <p>20 hazard-based association. And I've seen this</p> <p>21 in a review article around this topic from</p> <p>22 leading authors, leading experts in this</p> <p>23 area.</p> <p>24 So I would stand by that and</p>

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1 say, okay, they are a hazard-based
2 organization. They do base it on
3 classifications, more of yes/no, and also
4 subcategories. They do not talk about
5 concentration; that's risk. They do not
6 talking about concentration. They say
7 something's carcinogenic, it is or is not
8 carcinogenic; that's hazard. Where they
9 classify something as carcinogenic, something
10 is probably carcinogenic; that's hazard.
11 We're talking about risk.
12 We're talking about concentrations. We're
13 talking about exposure limits of the human
14 population at levels below these are
15 confident that we've shown that they do not
16 have increased risk. That's risk.
17 Q. You mentioned a paper -- who is
18 one of the authors that you're referring to?
19 A. I forget the first author, but
20 I'm aware that Alan Boobis is one of the
21 coauthors. I know of his work very well. I
22 think he still chairs the Committee of
23 Carcinogenicity in the U.K. He's also
24 writing a document in line with much of this

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1 work, actually, for environmental exposures
2 for the WHO.
3 Another coauthor, I think, is
4 Rita Schoeny, who was actually on the HESI
5 GTTC with us, and she represented EPA at that
6 time. And now she is -- I think she's
7 retired, probably retired, unlike many
8 scientists in this sort of area who keep
9 going. And some other authors.
10 So yes, those two highlights
11 for us to be able to get that publication
12 would be Alan Boobis and Rita Schoeny, and it
13 really explains very nicely the difference
14 between hazard and risk, and also states
15 quite clearly what the definitions around
16 IARC actually are and to point directly that
17 they're hazard and they do not talk about
18 risk around concentrations.
19 Q. Is the paper you're referring
20 to the Codification of Hazard and Its Impact
21 on the Hazard Versus Risk Controversy, John
22 Doe -- John Doe being the first author?
23 A. That is the correct paper.
24 Q. And Alan Boobies.

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1 A. No, not Boobies. Boobis.
2 Q. Oh, excuse me.
3 And Rita Schoeny is on here.
4 But this is the paper you were referencing?
5 A. That is the paper. And many of
6 the other coauthors are incredible, including
7 Sam Cohen.
8 MS. LOCKARD: Can we get this
9 pulled up as an exhibit, please, as
10 the next exhibit?
11 MR. HARKINS: Chris, this will
12 be 210 from our internal tracking,
13 introduced as Exhibit 41.
14 (Whereupon, Deposition Exhibit
15 Johnson-41, The codification of hazard
16 and its impact on the hazard versus
17 risk controversy, by Doe et al, was
18 marked for identification.)
19 BY MS. LOCKARD:
20 Q. So in the introduction section
21 of this, if you can just pull that up on the
22 screen, right there -- right there. So at
23 the very bottom, it says: There has been a
24 long-running controversy about the relative

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1 merits of hazard-based versus risk-based
2 approaches in managing the potential harm --
3 the potential for harm to human health from
4 the use of chemicals.
5 Do you agree with that?
6 A. I fully agree with that, and
7 that's a very nice statement.
8 Q. It goes on to say, page 2,
9 probably about six lines -- five or six lines
10 down -- it says: This can result in
11 inappropriate levels of concern, either too
12 much or too little, over some chemicals due
13 to factors such as perception of no choice in
14 exposure, poorly understood technical issues
15 such as dose response, unfamiliarity with
16 uses and benefits, and political desire to
17 ban or to keep in use.
18 Do you agree with that?
19 A. I entirely agree with that.
20 And going with just a hazard-based assessment
21 for regulating substances is absurd. To say
22 in coffee there's 21 known carcinogens. Do
23 we ban coffee? No. We figure out that
24 they're low concentrations, they're of

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1 negligible concern.
 2 We ban -- if we say something
 3 is a carcinogen -- IARC came out and said
 4 meat was a carcinogen. Do we ban meat? No.
 5 We start -- we go towards levels of risk.
 6 That's what we do.
 7 We've got to get towards dose
 8 response. We've got to get towards
 9 concentrations. We've got to get towards
 10 risk-based approaches.
 11 And this is why experts such as
 12 this need to put these publications out
 13 there, to really inform everyone and educate
 14 everyone. The media don't understand this.
 15 And this is why one week they'll say this
 16 gives you cancer, gets everyone scared.
 17 We don't need to go along those
 18 lines. We talk about dose. We talk about
 19 risk. And it's a big deal. We need to start
 20 talking about risk and move away from that
 21 hazard-based binary classification or
 22 subclassifications, as in IARC.
 23 Q. And is IARC making that
 24 movement away from the binary towards a

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1 dose-based assessment, or is it still binary?
 2 A. As far as I'm aware, it's --
 3 it's not so binary, because they've got four
 4 different options, but it's still
 5 classifications of hazard, definitely hazard.
 6 They do not talk about risk assessment
 7 levels. They're a hazard-based organization
 8 as reflected by their recent acknowledgement
 9 in this, that's also stated in this
 10 publication.
 11 Q. Is that on page -- if we
 12 could -- well, it's not -- I guess keep
 13 moving forward --
 14 A. I think it's like page 4 or 5,
 15 maybe.
 16 Q. -- to the section on
 17 carcinogenicity. There you go. Yeah.
 18 So is this the section that
 19 you're referring to, Dr. Johnson, regarding
 20 the IARC?
 21 A. Yes. This is a very nice --
 22 Q. What is this --
 23 A. -- clear statement.
 24 Q. What are they saying in this

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1 statement?
 2 MS. BOGDAN: Objection to form,
 3 speculative.
 4 BY MS. LOCKARD:
 5 Q. What do you understand this
 6 passage to mean --
 7 A. I'm looking at the Zoom. Can I
 8 see the whole Zoom? Keep going.
 9 THE WITNESS: Apologies,
 10 Victoria.
 11 I can't control the Zoom. I
 12 can't see the whole thing.
 13 MS. LOCKARD: Can I just give
 14 you a copy?
 15 THE WITNESS: Yeah, thank you.
 16 Great, thank you.
 17 A. My interpretation of this
 18 highlighted section within this excellent
 19 publication, around IARC. Statement: In
 20 fact, IARC's grouping is based on the
 21 strength of evidence as to whether a hazard
 22 is possible, not to the degree of hazard.
 23 This is a statement associated
 24 with IARC 2019 as well. We see these

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1 classifications, which have come up regularly
 2 in our discussions, around these different
 3 hazard-based categories for carcinogens.
 4 Group 1, Group 2A, Group 2B, Group 3.
 5 The next bit: The assessment
 6 is at Level 1, and this has been confirmed in
 7 the change to the name of the IARC monograph
 8 program in 2019, when Evaluation of
 9 Carcinogenic Risks -- because it wasn't
 10 risks -- became Identification of
 11 Carcinogenic Hazards -- because it's hazards,
 12 as I've stated.
 13 IARC emphasizes the point that
 14 they are operating Level 1 hazard
 15 codification: The categories of the
 16 classification refer to the strength of the
 17 evidence that an exposure is carcinogenic --
 18 it is carcinogenic and not to the risk of
 19 cancer from that particular exposure.
 20 They don't talk about dose,
 21 they don't talk about exposures, they don't
 22 talk about risk.
 23 The terms "probably
 24 carcinogenic" and "possibly carcinogenic"

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1 have no quantitative significance -- no
 2 quantitative significance -- and are used as
 3 descriptors of different strengths of
 4 evidence of carcinogenicity in humans;
 5 "probably carcinogenic" signifies a greater
 6 strength of evidence, and so on.
 7 So clearly stating here, which
 8 no one who understands this would disagree
 9 with, it's a hazard-based organization that
 10 does not talk about dose, does not talk about
 11 risk. And I wanted to make that clear.
 12 Q. Do you understand the meaning
 13 of the phrase "general causation" in the
 14 context of this case?
 15 MS. BOGDAN: Objection to the
 16 form, calls for a legal conclusion.
 17 BY MS. LOCKARD:
 18 Q. Do you understand, Dr. Johnson,
 19 that you've been identified as an expert on
 20 behalf of the defendants to provide general
 21 causation opinions?
 22 A. I have been made aware of that
 23 by GT.
 24 Q. Yes. And what -- if you could

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1 encapsulate your opinion for us today
 2 succinctly, what is your ultimate conclusion
 3 with respect to the question of general
 4 causation in this case?
 5 A. My conclusion --
 6 MS. BOGDAN: Objection to the
 7 form.
 8 A. My conclusion is that the
 9 individuals exposed to the levels of NDMA and
 10 NDEA that I've seen in these -- as impurities
 11 in these particular drugs does not cause
 12 increased risk to these exposed populations.
 13 That's my statement on that.
 14 BY MS. LOCKARD:
 15 Q. You've seen corporate documents
 16 reflecting levels of nitrosamine impurities
 17 in the products that are higher than the FDA
 18 chart; is that -- did you testify to that
 19 earlier?
 20 Let me ask it this way: Have
 21 you seen corporate documents showing the
 22 finished dose and API testing in this case
 23 from the corporate defendants?
 24 A. I have seen that information in

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1 lots of detail and discussed it as well as
 2 seeing it with those defendants too.
 3 Q. And in looking at those levels
 4 that were provided by the corporate
 5 defendants, despite some of them potentially
 6 being higher than levels reported by the FDA,
 7 did that change your opinion with respect to
 8 causation in your PDE calculation in this
 9 case?
 10 MS. BOGDAN: Objection to the
 11 form.
 12 A. It did not change my opinion
 13 about my conclusions, as just stated, in this
 14 case.
 15 BY MS. LOCKARD:
 16 Q. And you were shown an EMA
 17 document today that included testing from
 18 products sold in Europe.
 19 Do you recall seeing that
 20 document?
 21 A. From EMA?
 22 Q. Let's see if we can pull it up.
 23 A. Apologies, can you repeat the
 24 question?

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1 Q. I was trying to reference back
 2 to the EMA document that counsel showed you
 3 that included -- included a chart of levels
 4 from --
 5 A. I remember that now. Thank
 6 you.
 7 Q. Okay.
 8 A. I remember that.
 9 Q. And you did not include those
 10 levels in your risk assessment for this case,
 11 did you?
 12 A. I did not include those but I
 13 considered them.
 14 Q. But in your -- in performing
 15 your risk assessment with respect to this
 16 case and the individuals involved, would it
 17 have been appropriate for you to base your
 18 risk assessment on testing levels for
 19 products that were sold in an entirely
 20 different country than those at issue in this
 21 case?
 22 A. I like to deal with relevance
 23 and precision, and you'd need to base your
 24 assumptions on the country where those

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1 products are sold and where that batch has
2 been tested.
3 And basing that on a different
4 continent where it's different batches,
5 et cetera, different population, we would go
6 with the American numbers, not the EU
7 numbers.
8 Q. And you have seen American
9 numbers from both the corporate defendants
10 and the FDA; is that true?
11 A. That is true. The FDA ones are
12 in my report, and from the list, we can see
13 I've looked at and I've also discussed this
14 with the other companies too, through links
15 with GT too. So yes, I'm confident with
16 that.
17 Q. So when you referenced the
18 other companies, you've had discussions with
19 the lawyers for the companies for which
20 you're serving as an expert, but you haven't
21 spoken directly to industry people at these
22 pharmaceutical companies, have you?
23 A. That is correct.
24 Q. And I know there was a lot of

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1 discussion about how and when you were first
2 retained, but to clarify, when you were first
3 retained in this case as a consultant, that
4 retention came through Greenberg Traurig; is
5 that your recollection?
6 A. That is my recollection.
7 Q. So was there ever a time when
8 you were doing independent consultancy or
9 investigative work for Teva when the law firm
10 of GT was not involved?
11 A. No, it was always with GT.
12 MS. LOCKARD: Let's get marked
13 the next exhibit, please. We'll get
14 that pulled up on the screen.
15 (Whereupon, Deposition Exhibit
16 Johnson-42, E-mail(s) re: Snodin &
17 Elder Commentary,
18 TEVA-MDL2875-00425960, was marked for
19 identification.)
20 THE STENOGRAPHER: It's going
21 to be 42.
22 MR. HARKINS: Chris, this will
23 be 204 on our internal tracking.
24 ///

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1 BY MS. LOCKARD:
2 Q. Do you recall being asked
3 questions by counsel about an e-mail exchange
4 wherein Dr. Nudelman sent you a document and
5 said to find enclosed a new commentary from
6 Snodin and Elder?
7 Do you remember that e-mail?
8 A. I do remember we discussed that
9 yesterday.
10 Q. And that -- the e-mail that you
11 were asked to speculate about what you would
12 have put in your response to Dr. Nudelman, do
13 you recall that?
14 A. It was along the lines of thank
15 you for the paper.
16 Q. Okay. And I'm going to show
17 you what's been marked as the next exhibit in
18 line, and if you'll take a look at it.
19 MS. LOCKARD: This is now an
20 unredacted version, which I've had my
21 team look at the document that was
22 produced, and I'm unsure why it was
23 redacted, but it is now -- we have
24 dedesignated it as a redacted

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1 document. It's not privileged, and
2 it's not confidential, so we've
3 dedesignated on both sides.
4 BY MS. LOCKARD:
5 Q. But you haven't seen this -- I
6 haven't shown you this, have I?
7 A. No, I saw it yesterday with
8 redacted written on it, I think, as far as I
9 can recall.
10 Q. And this is -- is this the
11 first time you're seeing your actual words
12 since you wrote it?
13 A. Since -- yeah.
14 Q. Okay. So can you just read
15 into the record, what did you, in fact, say
16 to Dr. Nudelman after he sent you that
17 attachment?
18 A. I responded after I had been
19 passed on the paper, Snodin & Elder
20 Commentary: Hi, Raphy. Thank you for this.
21 Best wishes, George.
22 Succinct, maybe impolite, but
23 that's my response.
24 MS. LOCKARD: I wanted to have

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1 marked the Defendants' Responses and
2 Objections to Plaintiffs' Notice of
3 Videotaped Deposition.
4 MR. HARKINS: Chris, this will
5 be 200 on the internal tracking.
6 (Whereupon, Deposition Exhibit
7 Johnson-43, Defendants' Responses and
8 Objections to Plaintiffs' Notice of
9 Videotaped Deposition of George
10 Johnson, Ph.D., was marked for
11 identification.)
12 MS. LOCKARD: That's just for
13 the record.
14 BY MS. LOCKARD:
15 Q. We've been discussing that --
16 that the ICH MC -- excuse me, the ICH M7
17 provides for both options, doing the TD50 or
18 a PDE; is that correct?
19 A. Yes, that is correct.
20 Q. Do you have a copy of --
21 actually, I think this is your copy.
22 MS. LOCKARD: So, Steve, can we
23 bring up the ICH M7(R1) as the next
24 exhibit in line?

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1 MR. HARKINS: Chris, that will
2 be 209 from the internal tracking. If
3 you can please screen-share.
4 (Whereupon, Deposition Exhibit
5 Johnson-44, ICH Guideline, Assessment
6 and Control of DNA Reactive
7 (Mutagenic) Impurities in
8 Pharmaceuticals to Limit Potential
9 Carcinogenic Risk M7(R1), was marked
10 for identification.)
11 BY MS. LOCKARD:
12 Q. Can you identify for us,
13 Dr. Johnson, where in the ICH guideline it
14 addresses the PDE as being an acceptable
15 approach?
16 A. I think it's best explained on
17 page 35, Section 3, Nonlinear, brackets,
18 Threshold, Mode of Action and Calculation of
19 PDE.
20 Q. So that is the section you're
21 referring to, 35, page 35?
22 A. Page 35, about halfway down.
23 The Zoom has not moved on yet.
24 TRIAL TECHNICIAN: Hang on one

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1 second.
2 BY MS. LOCKARD:
3 Q. Okay. And what -- you know,
4 for purposes of this case, what does this
5 section tell us about the acceptability of
6 the use of a PDE?
7 A. I would like to read this
8 section to ensure precision.
9 The existence of mechanisms
10 leading to a dose response that is nonlinear
11 or has the -- or has a practical threshold --
12 (Audio malfunction.)
13 A. The existence of mechanisms
14 leading to a dose response that is nonlinear
15 or has a practical threshold is increasingly
16 recognized, not only for compounds that
17 interact with non-DNA targets but also for
18 DNA-reactive compounds.
19 For the record, in addition to
20 this, that includes the compounds we're
21 talking about today.
22 Keep reading: whose effects
23 may be modulated by, for example, rapid
24 detoxification before coming into contact

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1 with DNA, or by effective repair of induced
2 damage.
3 This statement is very
4 important for us. And then: The regulatory
5 approach to such compounds can be based on
6 the identification of a No-Observed Effect
7 Level -- notes that the BMD is equivalent to
8 the No-Observed Effect Level -- and use of
9 uncertainty factors, which we talked about a
10 lot, to calculate a permissible daily
11 exposure, a PDE.
12 This directly says if you can
13 understand the dose response, can show
14 nonlinearity or practical threshold, and you
15 can show that DNA repair is the mechanism,
16 then you can use a PDE.
17 Q. Thank you, Doctor.
18 A. An extension to that, the next
19 statement links entirely to my impact story
20 on EMS. An example of a DNA -- so the
21 example they use here: The example of a
22 DNA-reactive chemical for which a threshold
23 has been proposed for mutagenicity in vitro
24 and in vitro is ethyl methanesulfonate. A

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1 PDE calculation using uncertainty factors,
 2 instead of a linear extrapolation, is
 3 appropriate in such cases where a
 4 threshold -- and then a definition of
 5 threshold with mechanism above -- where a
 6 threshold has been established.
 7 This is entirely what I'm
 8 talking about and is in the ICH M7 guidance.
 9 Thank you.
 10 An extension -- do I need to
 11 explain what the ICH is?
 12 Q. No, that's okay. I think we
 13 get the point. I appreciate it, though.
 14 MS. LOCKARD: Let's just take a
 15 break. I think we've been going for a
 16 while. And I'll have a few more
 17 questions after that, but I should be
 18 getting close to done.
 19 THE VIDEOGRAPHER: Going off
 20 the record. The time is 2:32 p.m.
 21 (Recess taken, 2:32 p.m. to
 22 2:43 p.m. BST)
 23 THE VIDEOGRAPHER: We're back
 24 on the record. The time is 2:43 p.m.

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1 MS. LOCKARD: Okay. So I'd
 2 like to get marked as the next exhibit
 3 in line. It's just the -- it's a
 4 Second Amended List of Materials, for
 5 the record, which has the addition of
 6 the Chart of Weights and the CDC
 7 publicly available data that he had
 8 looked at online.
 9 (Whereupon, Deposition Exhibit
 10 Johnson-45, Johnson Second Amended
 11 List of Materials Considered, was
 12 marked for identification.)
 13 MS. LOCKARD: So I'll mark this
 14 second exhibit -- excuse me -- Second
 15 Amended List of Materials Considered
 16 as the next exhibit. And what number
 17 was that?
 18 THE STENOGRAPHER: 45.
 19 MS. LOCKARD: 45.
 20 So then for 46, I have a USB
 21 that contains everything that is on
 22 the Second Amended List of Materials
 23 Considered, including the weights
 24 chart and the CDC materials. So I'll

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1 mark the -- the thumb drive as
 2 Exhibit 46.
 3 (Whereupon, Deposition Exhibit
 4 Johnson-46, USB Drive of Documents
 5 Considered [Physical Exhibit], was
 6 marked for identification.)
 7 MS. LOCKARD: And I can give
 8 that to the court reporter after
 9 Zoom -- the videographer. Okay.
 10 At this time, I don't have any
 11 further questions, so I turn the
 12 witness back over to plaintiffs'
 13 counsel.
 14 MS. GOLDENBERG: Victoria, just
 15 because I saw the videographer shake
 16 his head, I don't think we can give
 17 him exhibits. Is there a way to get
 18 that to --
 19 MS. LOCKARD: Do you want to
 20 take it or --
 21 (Interruption by the
 22 stenographer.)
 23 (Technical comments off the
 24 stenographic record.)

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1 MS. LOCKARD: Okay. Thank you,
 2 Dr. Johnson.
 3 THE WITNESS: Thank you.
 4 MS. BOGDAN: I'm going to take
 5 just 10 minutes. Thank you.
 6 MS. LOCKARD: Okay.
 7 THE VIDEOGRAPHER: Going off
 8 the record. The time is 2:45 p.m.
 9 (Recess taken, 2:45 p.m. to
 10 2:59 p.m. BST)
 11 THE VIDEOGRAPHER: Back on the
 12 record. The time is 2:59 p.m.
 13 -----
 14 EXAMINATION
 15 -----
 16 BY MS. BOGDAN:
 17 Q. Hi, Doctor. I have some
 18 follow-up questions for you based upon your
 19 testimony that you just provided.
 20 Do you recall telling the
 21 defendants' lawyer that your mom took
 22 valsartan?
 23 A. Yes, that's a correct statement
 24 for myself.

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1 Q. Do you know whether your mom
 2 was taking contaminated valsartan?
 3 A. I do not know which version of
 4 valsartan she did. She would take them and
 5 throw the box away, and she was moved to a
 6 different drug. And when I talked to her,
 7 she had no boxes or recollection of which
 8 one.
 9 Q. Now, when you say she was moved
 10 to a different drug, was that in response to
 11 the valsartan recall?
 12 A. As far as I understand, yes.
 13 Q. And how much NDMA or NDEA was
 14 in the valsartan that your mom took?
 15 A. I do not know.
 16 MS. LOCKARD: Objection, form,
 17 speculation.
 18 A. I do not know.
 19 BY MS. BOGDAN:
 20 Q. And you do not know the
 21 manufacturer of the valsartan that your mom
 22 did take?
 23 A. That is correct, I do not know.
 24 Q. So you never attempted to order

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1 her pharmacy records to figure out who
 2 manufactured the valsartan that your mother
 3 took?
 4 MS. LOCKARD: I'm going to
 5 object to the extent that we're
 6 getting into any sort of -- it's not
 7 HIPAA protected, but in the European
 8 Union, the privacy restrictions are
 9 very strict.
 10 And if you want to make the
 11 record with your questions, but I'm
 12 uncomfortable with him answering
 13 questions about his mother's health
 14 and pharmacy records.
 15 MS. BOGDAN: Well, he is the
 16 one that brought it up in his redirect
 17 testimony, and I'm not asking about
 18 what the records say.
 19 What I'm asking is if he took
 20 the steps to get his mother's pharmacy
 21 records and review them, not what they
 22 say. It's if he actually took that
 23 action himself. That is the question
 24 on the table.

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1 MS. LOCKARD: I'll allow that.
 2 You can answer.
 3 THE WITNESS: Okay.
 4 A. I did not take those steps to
 5 get the pharmacy records of which batches and
 6 so on or producers of valsartan she was
 7 taking because I was comfortable that she had
 8 no increased risk of cancer, so I did not
 9 perform that action.
 10 BY MS. BOGDAN:
 11 Q. Now, in response to the defense
 12 lawyer's questions, you spoke a little bit
 13 about DNA repair.
 14 DNA repair genes frequently
 15 express reduced levels of repair proteins due
 16 to epigenetic repression, correct?
 17 A. Certain DNA repair genes would
 18 have different levels for -- and epigenetic
 19 modifications could be one such mechanism for
 20 reducing their levels, correct.
 21 Q. This can lead to increased DNA
 22 damage, correct?
 23 A. Depending on which DNA repair
 24 enzyme was being modified, some would be

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1 correct, some would have less influence.
 2 Q. And increased DNA damage can
 3 lead to increased mutations, correct?
 4 A. Increased DNA damage can lead
 5 to increased mutations.
 6 Q. The epigenetic repression or
 7 DNA gene expression is also frequent in the
 8 field defects that surround and give rise to
 9 cancer, correct? Let me rephrase that.
 10 The epigenetic repression or
 11 DNA repair gene expression is also frequent
 12 in the field defects that surround and give
 13 rise to cancer, correct?
 14 A. It could be one characteristic
 15 of a cancer, to have different levels of DNA
 16 repair, with potentially epigenetics being
 17 one such modification of a DNA repair enzyme.
 18 Q. And people inherit mutations in
 19 DNA repair genes, correct?
 20 MS. LOCKARD: Objection, vague.
 21 A. People can inherit certain
 22 modifications in certain DNA repair genes,
 23 unless that modification leads to their death
 24 before they produce a child, if it's a very

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1 severe and important DNA repair gene.
2 BY MS. BOGDAN:
3 Q. MGMT expression can be reduced
4 due to methylation of the MGMT promoter
5 region, correct?
6 A. MGMT can be reduced by
7 methylation of the promoter region, so
8 reduction is different to being knockout and
9 not being existent, which is what I was
10 discussing with that adjustment factor of not
11 being there compared to lower amounts of that
12 DNA repair enzyme.
13 Q. And isn't it true that 40 to
14 90% of colorectal cancers have reduced MGMT
15 repression due to methylation of the MGMT
16 promoter region?
17 A. I'm unaware of that
18 information.
19 Q. And out of the millions of
20 users of valsartan, was it your testimony
21 that none of them have MGMT deficiency?
22 MS. LOCKARD: Object to form.
23 A. My comment around this topic
24 was a small proportion of people that we

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1 could potentially investigate that would be
2 linked to this particular case. Within that
3 small population, the probability of someone
4 having no MGMT at all would be highly
5 unlikely.
6 BY MS. BOGDAN:
7 Q. And so you were referring to no
8 MGMT --
9 (Clarification requested by the
10 stenographer.)
11 BY MS. BOGDAN:
12 Q. -- in your previous testimony?
13 A. In my previous testimony, I was
14 referring to no, so absent or -- yeah, so
15 absent DNA repair, specifically MGMT, and the
16 reason why I stated that exactly is because
17 in that White, et al paper where we looked at
18 the difference that knockout, so absence of
19 MGMT, had on the influence of toxic and
20 genotoxic effect was within this factor of
21 10. So even full absence of DNA repair,
22 specifically MGMT, the maximum response we
23 could see was around 10, and anything beyond
24 that means that that factor should be --

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1 could be reduced from that number of 10. So
2 that's what I was referring to.
3 Q. So you acknowledge that
4 patients can have a reduced MGMT expression
5 due to methylation of the MGMT in the
6 promoter region, correct?
7 A. I accept that that is a
8 possibility, correct.
9 Q. And you haven't reviewed all of
10 the plaintiffs' medical records in this
11 litigation, correct?
12 A. I have not reviewed all of the
13 patients' medical records. That is
14 definitely correct.
15 Q. So you wouldn't know whether
16 any of the plaintiffs actually have MGMT
17 deficiency, correct?
18 A. I would not know that, and that
19 would be an assumption. Hence, when I
20 discussed it, it was presented as an
21 assumption.
22 Q. Now, I believe Exhibit 44 that
23 you were shown, which was the ICH M7
24 guidance, has a date on it of March of 2017?

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1 A. Are we getting this up on the
2 screen?
3 TRIAL TECHNICIAN: Yes.
4 BY MS. BOGDAN:
5 Q. Isn't that correct?
6 A. Can we put it as an exhibit as
7 well, please, and to keep things moving, I
8 can see on the screen that that is correct
9 from 2017, but I'd like to see it in the full
10 format in the exhibit too. This is correct.
11 TRIAL TECHNICIAN: It's in
12 there as Exhibit 44.
13 BY MS. BOGDAN:
14 Q. And this was the document that
15 you referenced with regard to the BMD
16 approach, correct?
17 A. This was the document that I
18 referred to for the PDE approach.
19 Q. For the PDE approach. Excuse
20 me. Right.
21 MS. BOGDAN: So we can take
22 that down.
23 BY MS. BOGDAN:
24 Q. And isn't it true that the

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1 guidance for industry that the FDA in this
2 country published for the control of
3 nitrosamine impurities in human drugs, dated
4 four years later, in February of 2021,
5 elected to follow the linear dose
6 extrapolation method to calculate acceptable
7 intake limits for NDMA and NDEA? Isn't that
8 correct?

9 MS. LOCKARD: Objection, form.

10 A. It is correct. Those FDA
11 decisions to calculate an acceptable intake
12 based on a linear back-extrapolation from the
13 harmonic mean of the TD50 for NDMA and NDEA,
14 to calculate those acceptable intakes, so
15 that was dated after this ICH guidance which
16 we were just looking at, ICH M7.

17 BY MS. BOGDAN:

18 Q. Would you agree that the United
19 States FDA is responsible for protecting
20 public health?

21 MS. LOCKARD: Objection, vague.

22 A. I would accept that that's one
23 of the remits of the FDA, as well as many
24 other regulatory bodies, to protect public

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1 health.

2 BY MS. BOGDAN:

3 Q. And that the FDA has
4 established the acceptable intake limits for
5 NDMA at 96 nanograms per day and NDEA at
6 26.5 nanograms per day; isn't that correct?

7 MS. LOCKARD: Objection, asked
8 and answered.

9 A. I'm aware that the FDA has
10 calculated NDMA acceptable intake based on
11 the linear back-extrapolation from the
12 harmonic mean of the TD50 in liver using a
13 1-in-100,000 approach with a linear
14 back-extrapolation and no correction from
15 animals to humans, no consideration of DNA
16 repair or dose response to calculate 96 for
17 NDMA and 26.5 acceptable intake for NDEA.
18 I -- yes.

19 BY MS. BOGDAN:

20 Q. And isn't it true that the FDA
21 has established 96 nanograms as the
22 acceptable daily limit for NDMA?

23 MS. LOCKARD: Objection, asked
24 and answered.

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1 BY MS. BOGDAN:

2 Q. That's a yes-or-no question.

3 A. NDMA -- the FDA has produced an
4 acceptable intake based on the linear
5 back-extrapolation from those data, and it is
6 96 for NDMA. That's the acceptable intake
7 from the FDA using that linear
8 back-extrapolation, correct.

9 Q. And similarly, the FDA has
10 established the acceptable limit for NDEA at
11 26.5 nanograms a day?

12 MS. LOCKARD: Objection, asked
13 and answered.

14 A. FDA has calculated and
15 presented and published the acceptable intake
16 of 26.5 for NDEA based on the linear
17 back-extrapolation calculation from the
18 harmonic mean of the TD50 using that approach
19 that I've critiqued heavily.

20 MS. BOGDAN: I don't have any
21 further questions at this time.

22 MS. LOCKARD: Okay. Quick
23 break.

24 THE VIDEOGRAPHER: Going off

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1 the record. The time is 3:15 p.m.
2 (Recess taken, 3:15 p.m. to
3 3:19 p.m. BST)

4 THE VIDEOGRAPHER: Back on the
5 record. The time is 3:19 p.m.

6 MS. LOCKARD: Okay. I don't
7 have any more questions for you,
8 Dr. Johnson. Thank you very much. I
9 think this means your deposition is
10 concluded.

11 We previously indicated we
12 would designate the deposition at the
13 end of the 30-day period with respect
14 to confidentiality, and it's deemed
15 under the protective order
16 confidential for the next 30 days
17 until we do so.

18 THE STENOGRAPHER: Anything
19 else?

20 MS. LOCKARD: Nope. Thank you.

21 THE VIDEOGRAPHER: Going off
22 the record. The time is 3:20 p.m.
23 (Time noted: 3:20 p.m. BST)
24 --o0o--

1 CERTIFICATE
2 I, MICHAEL E. MILLER, Fellow of
3 the Academy of Professional Reporters,
4 Registered Diplomate Reporter, Certified
5 Realtime Reporter, Certified Court Reporter
6 and Notary Public, do hereby certify that
7 prior to the commencement of the examination,
8 GEORGE JOHNSON, Ph.D. was duly sworn by me to
9 testify to the truth, the whole truth and
10 nothing but the truth.
11 I DO FURTHER CERTIFY that the
12 foregoing is a verbatim transcript of the
13 testimony as taken stenographically by and
14 before me at the time, place and on the date
15 hereinbefore set forth, to the best of my
16 ability.
17 I DO FURTHER CERTIFY that pursuant
18 to FRCP Rule 30, signature of the witness was
19 not requested by the witness or other party
20 before the conclusion of the deposition.
21 I DO FURTHER CERTIFY that I am
22 neither a relative nor employee nor attorney
23 nor counsel of any of the parties to this
24 action, and that I am neither a relative nor
25 employee of such attorney or counsel, and
26 that I am not financially interested in the
27 action.
28
29 MICHAEL E. MILLER, FAPR, RDR, CRR
30 Fellow of the Academy of Professional Reporters
31 NCRA Registered Diplomate Reporter
32 NCRA Certified Realtime Reporter
33 Certified Court Reporter
34
35 New Jersey Certified Court Reporter
36 No. 30XI00242200
37 Expires: 6/30/2022
38
39 Dated: October 12, 2021

1	ERRATA
2	PAGE LINE CHANGE
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INSTRUCTIONS TO WITNESS

3 Please read your deposition over
4 carefully and make any necessary corrections.
5 You should state the reason in the
6 appropriate space on the errata sheet for any
7 corrections that are made.

8 After doing so, please sign the
9 errata sheet and date it.

10 You are signing same subject to
11 the changes you have noted on the errata
12 sheet, which will be attached to your
13 deposition.

14 It is imperative that you return
15 the original errata sheet to the deposing
16 attorney within thirty (30) days of receipt
17 of the deposition transcript by you. If you
18 fail to do so, the deposition transcript may
19 be deemed to be accurate and may be used in
20 court.

ACKNOWLEDGMENT OF DEPONENT

I, GEORGE JOHNSON, Ph.D., do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

GEORGE JOHNSON, Ph.D. DATE

15 Subscribed and sworn to before me this
16 _____ day of _____, 20 _____.
17 My commission expires: _____

20 Notary Public

1	LAWYER'S NOTES		
2			
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Errata Sheet

October 4-5, 2021 Deposition Transcript – George Johnson, Ph.D.
In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation

MONDAY 10/4/21

Pages, Lines	Change:	Reason
64:24	Change “test” to “ testing ”	Clarification
83:23	Change “I’ve” to “ I ”	Clarification
94:10	Change “how it’s occurred” to “ how it occurs ”	Clarification
157:23	Change “slide date” to “slide deck ”	Clarification.
174:13	Change “replied” to “ replying ”	Clarification
192:6-7	“or if, as we predicted, the observed concentration would be below the PDE...”	Clarification
199:23	Change “contour” to “ quantal ”	Transcription error
205:12	Change “covariant” to “ covariate ”	Transcription error
219:17	Change “was” to “ were ”	Transcription error / Correction
258:20	“I did, (as in “what I did was”))” – should edit to say, “What I did was, I looked at	Transcription error / Correction

TUESDAY 10/5/21

Pages, Lines	Change:	Reason
328:2	Add: “and even then it will not be 100% pure.”	Completeness / clarification
340:22	Change “multiples suggested” to read “multiple <i>species</i> ” suggested by....	Transcription error / clarification.
351:11-13	Remove names; incorrect recollection, these persons not involved.	Correction
377:11-12	Change “lie to” and make it “ align with ”	Transcription error / correct testimony
379:3	Change “far” to “ for ”	Transcription error / correct testimony
381:6	Insert “ do not ” before have	Transcription error / correct testimony
384:5	Change 1-100 risk to 1-100,000	Transcription error / correct testimony
384:6	Change 1-100 risk to 1-100,000	Transcription error / correct testimony
387:1-2	Edit “That’s the background” to “ That’s the actual background rate of cancer. ”	Completeness and clarification
421:3	Delete “would be”	Correction / Clarification
445:20	Change “antigens” to “ aneugens ”	Transcription error / correct testimony

446:21	Change "vice president" to " past president "	Transcription error / correct testimony
460:1	Change "is it shows" to "is that it shows"	Clarification
463:12	Strike "I do"	Clarification
492:6	Change "talking" to " talk "	clarification
495:21	Change "To say" to " For example "	Clarification
507:13	Change "yeah" to " yes "	Proper English
518:24	Add comma after "would be,"	Clarification on sentence



George Johnson, Ph.D.

 , Notary Public.

This, the 17th day of November, 2021.

My Commission Expires:

